| 1  |                 | TITLE 68: PROFESSIONS AND OCCUPATIONS  |
|----|-----------------|--|
| 2  | CHAPTE          | R VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION                     |
| 3  |                 | SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS                                      |
| 4  |                 |  |
| 5  |                 | PART 1330  |
| 6  |                 | PHARMACY PRACTICE ACT  |
| 7  |                 |  |
| 8  |                 | SUBPART A: GENERAL PROVISIONS  |
| 9  |                 |  |
| 10 | Section         |  |
| 11 | 1330.10         | Definitions  |
| 12 | 1330.20         | Fees   |
| 13 | 1330.30         | Unprofessional and Unethical Conduct   |
| 14 | 1330.40         | Violations   |
| 15 | 1330.50         | Vaccinations/Immunizations   |
| 16 | 1330.60         | Internet Pharmacies  |
| 17 | 1330.70         | Granting Variances   |
| 18 | 1330.80         | Renewals   |
| 19 | 1330.90         | Restoration of a Pharmacist License  |
| 20 | 1330.100        | Continuing Education ("CE")  |
| 21 | 1330.110        | Confidentiality  |
| 22 |                 |  |
| 23 |                 | SUBPART B: PHARMACY TECHNICIAN   |
| 24 |                 |  |
| 25 | Section         |  |
| 26 | 1330.200        | Application for Certificate of Registration as a Pharmacy Technician           |
| 27 | 1330.210        | Pharmacy Technician Training   |
| 28 | 1330.220        | Application for Certificate of Registration as a Certified Pharmacy Technician |
| 29 | <u>1330.230</u> | Continuing Education ("CE") for Certified Pharmacy Technicians                 |
| 30 |                 |  |
| 31 |                 | SUBPART C: PHARMACIST  |
| 32 |                 |  |
| 33 | Section         |  |
| 34 | 1330.300        | Approval of Pharmacy Programs  |
| 35 | 1330.310        | Graduates of Programs Outside the United States                                |
| 36 | 1330.320        | Application for Examination  |
| 37 | 1330.330        | Examination for Licensure  |
| 38 | 1330.340        | Application for Licensure on the Basis of Examination                          |
| 39 | 1330.350        | Endorsement  |
| 40 | 1330.360        | <u>Pharmacy Residents</u>  |
| 41 |                 |  |
| 42 |                 | SUBPART D: PHARMACY LICENSURE  |
| 43 |                 |  |

| 44 | Section  |  |
|----|----------|--|
| 45 | 1330.400 | Application for a Pharmacy License   |
| 46 | 1330.410 | Pharmacy Licenses  |
| 47 | 1330.420 | Emergency Remote Temporary Pharmacy License  |
| 48 | 1330.120 | Emergency Remote Temporary Finantiacy Election   |
| 49 |          | SUBPART E: TYPES OF PHARMACIES   |
| 50 | Section  |  |
| 51 | 1330.500 | Community Pharmacy Services  |
| 52 | 1330.510 | Telepharmacy   |
| 53 | 1330.520 | Offsite Institutional Pharmacy Services  |
| 54 | 1330.530 | Onsite Institutional Pharmacy Services   |
| 55 | 1330.540 | Nuclear Pharmacy Services  |
| 56 | 1330.550 | Nonresident Pharmacies   |
| 57 | 1330.560 | Remote Prescription/Medication Order Processing  |
| 58 |          |  |
| 59 |          | SUBPART F: PHARMACY STANDARDS  |
| 60 |          |  |
| 61 | Section  |  |
| 62 | 1330.600 | Security Requirements  |
| 63 | 1330.610 | Pharmacy Structural/Equipment Standards  |
| 64 | 1330.620 | Electronic Equipment Requirements for Remote Pharmacies                                |
| 65 | 1330.630 | Sanitary Standards   |
| 66 | 1330.640 | Pharmaceutical Compounding Standards   |
| 67 | 1330.650 | Pharmacy Computer Regulations  |
| 68 | 1330.660 | Pharmacist-in-Charge   |
| 69 | 1330.670 | Compounded Sterile Preparation Standards (Repealed)                                    |
| 70 | 1330.680 | Automated Dispensing and Storage Systems   |
| 71 |          |  |
| 72 |          | SUBPART G: PHARMACY OPERATIONS   |
| 73 |          |  |
| 74 | Section  |  |
| 75 | 1330.700 | Patient Counseling   |
| 76 | 1330.710 | Reporting Theft or Loss of Controlled Substances                                       |
| 77 | 1330.720 | Transfer of Prescription   |
| 78 | 1330.730 | Drug Prepackaging  |
| 79 | 1330.740 | Multi-Med Dispensing Standards for Community Pharmacies                                |
| 80 | 1330.750 | Return of Drugs  |
| 81 | 1330.760 | Electronic Transmission of Prescriptions   |
| 82 | 1330.765 | Requirements for Enrollment in Automated Prescription Refill Programs                  |
| 83 | 1330.770 | Centralized Prescription Filling   |
| 84 | 1330.780 | <u>Changes</u> of Ownership, <u>Name</u> , <u>Location or Operations</u> of a Pharmacy |
| 85 | 1330.790 | Closing a Pharmacy   |
| 86 | 1330.800 | Pharmacy Self-Inspection   |

87 88 AUTHORITY: Implementing the Pharmacy Practice Act [225 ILCS 85] and authorized by 89 Section 2105-15 of the Civil Administrative Code of Illinois [20 ILCS 2105/2105-15]. 90 91 SOURCE: Rules and Regulations Promulgated for the Administration of the Illinois Pharmacy 92 Practice Act, effective August 20, 1975; amended March 8, 1977; amended at 4 Ill. Reg. 1234, 93 effective July 11, 1980; amended at 5 Ill. Reg. 2997, effective March 11, 1981; codified at 5 Ill. 94 Reg. 11049; emergency amendment at 6 Ill. Reg. 916, effective January 6, 1982, for a maximum 95 of 150 days; amended at 6 Ill. Reg. 7448, effective June 15, 1982; amended at 7 Ill. Reg. 6496, 96 effective June 30, 1983; amended at 9 III. Reg. 16918, effective October 23, 1985; amended at 97 10 Ill. Reg. 21913, effective December 17, 1986; transferred from Chapter I, 68 Ill. Adm. Code 98 330 (Department of Registration and Education) to Chapter VII, 68 Ill. Adm. Code 1330 99 (Department of Professional Regulation) pursuant to P.A. 85-225, effective January 1, 1988, at 100 12 Ill. Reg. 2957; amended at 12 Ill. Reg. 17394, effective October 14, 1988; amended at 16 Ill. 101 Reg. 19811, effective December 7, 1992; amended at 21 Ill. Reg. 12600, effective August 29, 102 1997; amended at 22 III. Reg. 21959, effective December 1, 1998; amended at 23 III. Reg. 103 14131, effective November 18, 1999; amended at 24 Ill. Reg. 8548, effective June 9, 2000; 104 amended at 26 Ill. Reg. 18338, effective December 13, 2002; amended at 27 Ill. Reg. 19389, 105 effective December 11, 2003; emergency amendment at 29 Ill. Reg. 5586, effective April 1, 106 2005, for a maximum of 150 days; amended at 29 Ill. Reg. 13639, effective August 25, 2005; 107 amended at 30 Ill. Reg. 14267, effective August 21, 2006; amended at 30 Ill. Reg. 16930, effective October 12, 2006; emergency amendment at 31 III. Reg. 16045, effective November 19, 108 109 2007, for a maximum of 150 days; amended at 32 Ill. Reg. 3262, effective February 21, 2008; 110 amended at 32 Ill. Reg. 7116, effective April 16, 2008; old Part repealed at 34 Ill. Reg. 6688, 111 effective April 29, 2010; new Part adopted at 34 Ill. Reg. 6690, effective April 29, 2010; 112 amended at 39 Ill. Reg. 6267, effective April 23, 2015; amended at 41 Ill. Reg. 10643, effective 113 August 18, 2017; amended at 42 III. Reg. 20022, effective November 9, 2018; amended at 47 III. 114 Reg. \_\_\_\_\_\_, effective \_\_\_\_\_\_. 115 116 SUBPART A: GENERAL PROVISIONS 117 118 Section 1330.20 Fees 119 120 The following fees are not refundable: 121 122 Registration as a Pharmacy Technician, Student Pharmacist or Certified Pharmacy a) 123 Technician

The fee for application for a certificate of registration as a pharmacy

technician or certified pharmacy technician is \$40.

124 125

126

127

1)

| 128<br>129<br>130 |    | 2)            | The fee for the renewal of a certificate of registration as a pharmacy technician, student pharmacist or certified pharmacy technician shall be calculated at the rate of \$25 per year. |
|-------------------|----|---------------|--|
| 131<br>132        | b) | Licen         | se as a Pharmacist   |
| 133               | 0) | Licen         |  |
| 34                |    | 1)            | The fee for application for a license as a pharmacist is \$75.   |
| 35                |    | 1)            | The fee for application for a freelise as a pharmacist is \$\psi_{70}\$.   |
| 136               |    | 2)            | In addition, applicants for any examination as a registered pharmacist shall   |
| 137               |    | -/            | be required to pay, either to the Division or to the designated testing  |
| 38                |    |               | service, a fee covering the cost of determining an applicant's eligibility   |
| 39                |    |               | and providing the examination. Failure to appear for the examination on  |
| 40                |    |               | the scheduled date, at the time and place specified, after the applicant's   |
| 41                |    |               | application for examination has been received and acknowledged by the  |
| 42                |    |               | Division or the designated testing service, shall result in the forfeiture of  |
| 43                |    |               | the examination fee.   |
| 44                |    |               |  |
| 45                |    | 3)            | The fee for a license as a registered pharmacist, registered or licensed   |
| 46                |    | ,             | under the laws of another state or territory of the United States, is \$200.   |
| 47                |    |               | •  |
| 48                |    | 4)            | The fee for the renewal of a license shall be calculated at the rate of \$75   |
| 49                |    |               | per year.  |
| 50                |    |               |  |
| 51                |    | 5)            | The fee for the restoration of a license other than from inactive status is  |
| 52                |    |               | \$50 plus all lapsed renewal fees, not to exceed \$450.  |
| 153               |    |               |  |
| 54                |    | 6)            | Applicants for the preliminary diagnostic examination shall be required to   |
| 155               |    |               | pay, either to the Division or to the designated testing service, a fee  |
| 156               |    |               | covering the cost of determining an applicant's eligibility and providing  |
| 157               |    |               | the examination. Failure to appear for the examination on the scheduled  |
| 158               |    |               | date, at the time and place specified, after the application for examination   |
| 59                |    |               | has been received and acknowledged by the Division or the designated   |
| 60                |    |               | testing service, shall result in the forfeiture of the examination fee.  |
| 61                |    |               |  |
| 62                |    | <del>7)</del> | The fee to have the scoring of an examination authorized by the Division   |
| 163               |    |               | reviewed and verified is \$20 plus any fee charged by the applicable testing   |
| 64                |    |               | service.   |
| 165               |    |               |  |
| 166               | c) | Licen         | se as a Pharmacy   |
| 167               |    |               |  |
| 168               |    | 1)            | The fee for application for a license for a pharmacy under the Act is \$100.   |
| 169               |    |               |  |

| 170<br>171 |              | 2)                       | The fee for the renewal of a license for a pharmacy under the Act shall be calculated at the rate of \$100 per year. |
|------------|--------------|--------------------------|--|
| 172        |              |                          |  |
| 173        |              | 3)                       | The fee for the change of a pharmacist-in-charge is \$25.  |
| 174        |              |                          |  |
| 175        | d)           | Gene                     | eral Fees  |
| 176        |              |                          |  |
| 177        |              | 1)                       | The fee for the issuance of a duplicate license, for the issuance of a   |
| 178        |              |                          | replacement license for a license that has been lost or destroyed or for the   |
| 179        |              |                          | issuance of a license with a change of name or address other than during   |
| 180        |              |                          | the renewal period is \$20. No fee is required for name and address  |
| 181        |              |                          | changes on Division records when no duplicate certification is issued.   |
| 182        |              |                          |  |
| 183<br>184 |              | 2)                       | The fee for a certification of a registrant's record for any purpose is \$20.  |
| 185        |              | 3)                       | The fee to have the scoring of an examination administered by the  |
|            |              | 3)                       | Division reviewed and verified is \$20.  |
| 186        |              |                          | Division reviewed and vermed is \$20.  |
| 187        |              | 4)                       | The fee for a well confidence showing licensum on registration shall be the  |
| 188        |              | <del>4)</del>            | The fee for a wall certificate showing licensure or registration shall be the  |
| 189<br>190 |              |                          | actual cost of producing the certificate.  |
|            |              | 5)                       | The fee fee a restor of nersons registered as phorms sists or registered   |
| 191        |              | <del>5)</del>            | The fee for a roster of persons registered as pharmacists or registered  |
| 192        |              |                          | pharmacies in this State shall be the actual cost of producing the roster.   |
| 193        |              | 6)                       | The fee for sharmony licensing disciplinary or investigative records   |
| 194        |              | <del>6)</del>            | The fee for pharmacy licensing, disciplinary or investigative records  |
| 195        |              |                          | obtained pursuant to a subpoena is \$1 per page.   |
| 196        | (C           |                          | and of 47 III Dog offerting  |
| 197        | (Sour        | ce: An                   | nended at 47 Ill. Reg, effective)  |
| 198        | Spotion 1220 | ) <b>5</b> 0 <b>3</b> 7. | accinations/Immunizations  |
|            | section 1350 | ).50 V                   | accinations/infinumizations  |
| 200<br>201 | 0)           | Onel                     | ifications   |
| 201        | a)           | Quai                     | incations  |
| 202        |              | 1)                       | A pharmaciet, or a student pharmaciet or a pharmacy technician under the   |
| 203<br>204 |              | 1)                       | A pharmacist, or <u>a</u> student pharmacist <u>or a pharmacy technician</u> under the                               |
| 204        |              |                          | direct supervision of a pharmacist, may administer   |
|            |              |                          | vaccinations/immunizations to persons who are 714 years of age or older  |
| 206        |              |                          | pursuant to a valid patient specific prescription or a standing order by a   |
| 207        |              |                          | physician licensed to practice medicine in all of its branches under the   |
| 208        |              |                          | Medical Practice Act of 1987 [225 ILCS 60].  |
| 209        |              | 2)                       | A mhamma siat on atridant mhamma siat de de diseat   |
| 210        |              | <del>2)</del>            | A pharmacist, or student pharmacist under the direct supervision of a  |
| 211        |              |                          | pharmacist, may administer influenza (inactivated influenza vaccine and  |
| 212        |              |                          | live attenuated influenza intranasal vaccine) and Tdap (tetanus, diphtheria  |
|            |              |                          |  |

| 213        |    |                        | acellular pertussis) vaccines/immunizations to persons who are 10 to 13           |
|------------|----|------------------------|---|
| 214        |    |                        | years of age pursuant to a valid patient specific prescription or a standing      |
| 215        |    |                        | order by a physician licensed to practice medicine in all of its branches         |
| 216        |    |                        | under the Medical Practice Act of 1987.   |
| 217        |    |                        |   |
| 218        |    | <u>2</u> 3)            | The pharmacist, student pharmacist, or pharmacy technician shall                  |
| 219        |    | _ ′                    | successfully complete a course of training accredited by the Accreditation        |
| 220        |    |                        | Council on Pharmacy Education, or a similar health authority or                   |
| 221        |    |                        | professional body approved by the Division. The pharmacist who is                 |
| 222        |    |                        | responsible for supervising the pharmacy student or pharmacy technician           |
| 223        |    |                        | has the sole responsibility of evaluating the appropriateness of each             |
| 224        |    |                        | vaccination prior to its administration and maintains full responsibility and     |
| 225        |    |                        | oversight of the process.   |
| 226        |    |                        | o telegraphic de tale process.  |
| 227        |    | <u>3</u> 4)            | The pharmacist shall maintain a current Basic Life Support Certification          |
| 228        |    | <u>=</u> 1)            | for Healthcare Providers issued by the American Heart Association, the            |
| 229        |    |                        | American Red Cross, the American Safety and Health Institute, or an               |
| 230        |    |                        | equivalent as determined by the Division.   |
| 231        |    |                        | equivalent as determined by the Bivision.   |
| 232        |    | <u>4<del>5</del></u> ) | Each pharmacy, or pharmacist functioning outside of a pharmacy, shall             |
| 233        |    | <u></u>                | have available a current copy or electronic version of the CDC reference          |
| 234        |    |                        | "Epidemiology and Prevention of Vaccine – Preventable Diseases" at the            |
| 235        |    |                        | location where vaccinations are administered.                                     |
| 236        |    |                        | location where vaccinations are administered.                                     |
| 237        |    | <u>5</u> 6)            | The administration of vaccines shall be done by a pharmacist, or <u>a</u> student |
| 238        |    | <u>5</u> 0)            | pharmacist or pharmacy technician under the direct supervision of a               |
| 239        |    |                        | pharmacist, who has completed training as described in this section.              |
| 240        |    |                        | pharmacist, who has completed training as described in this section.              |
| 241        | b) | Protoc                 | cols, Policies and Procedures   |
| 242        | 0) | 110100                 | sois, I offices and I focedures   |
| 243        |    | 1)                     | Prior to administrating vaccinations/immunizations, a pharmacist, or a            |
| 244        |    | 1)                     | student pharmacist or a pharmacy technician under the direct supervision          |
| 245        |    |                        | of a pharmacist, must follow protocols written by a physician licensed to         |
| 246        |    |                        | practice medicine in all of its branches for the administration of vaccines       |
| 247        |    |                        | and treatment of severe adverse events following administration of                |
| 248        |    |                        | vaccines.   |
| 249        |    |                        | vaccines.   |
| 250        |    | 2)                     | The pharmacy must maintain written policies and procedures for handling           |
| 251        |    | 4)                     | and disposal of all used supplies or contaminated equipment.                      |
| 252        |    |                        | and disposal of an used supplies of containinated equipment.                      |
| 252<br>253 |    | 3)                     | The pharmacist, or student pharmacist under the direct supervision of a           |
| 253<br>254 |    | 3)                     | pharmacist, must give the appropriate vaccine information statement (VIS)         |
| 255        |    |                        | to the patient or legal representative prior to each vaccination. The             |
| 433        |    |                        | to the patient of legal representative prior to each vaccination. The             |

|              |              | pharm  | acist, or student pharmacist under the direct supervision of a  |
|--------------|--------------|--|---|
|              |              | pharm  | acist, must ensure that the adult patient or minor (age 710 and older   |
|              |              | for inf  | luenza and Tdap, age 14 and older for all other vaccines) patient's   |
|              |              |  | or legal representative is available and has the vaccine information  |
|              |              | statem   |   |
|              |              |  |   |
|              | 4)           | The pl   | harmacy must report adverse events as required by the Vaccine   |
|              | ,            | -  | rse Events Reporting System (VAERS) and to the primary care   |
|              |              |  | ler named by the patient.   |
|              |              | 1  | 7 1   |
| c)           | Reco         | rdkeepin   | g and Reporting   |
| ,            |              | 1  |   |
|              | 1)           | All red  | cords regarding each administration of a vaccine must be kept for 5   |
|              | ,            |  | These records shall include:  |
|              |              | J  |   |
|              |              | A)   | The name, address and date of birth of the patient.   |
|              |              | ,  | ,   |
|              |              | B)   | Date of administration and site of injection of the vaccine.  |
|              |              | ,  | <b></b>   |
|              |              | C)   | Name, dose, manufacturer, lot number and beyond use date of the   |
|              |              | - /  | vaccine.  |
|              |              |  |   |
|              |              | D)   | Name and address of the patient's primary health care provider  |
|              |              | ,  | named by the patient.   |
|              |              |  |   |
|              |              | E)   | The name or unique identifier of the administering pharmacist.  |
|              |              | ,  |   |
|              |              | F)   | Which vaccine information statement (VIS) was provided.   |
|              |              | ,  | `   |
|              | 2)           | A pha  | rmacist who administers or oversees the administration of any   |
|              | ,            | -  | ne must ensure that the report of that administration, is made within   |
|              |              |  | ys after the date of administration, to the Illinois Comprehensive  |
|              |              | •  | nated Immunization Registry Exchange (I-CARE) or to the patient's   |
|              |              |  | ry healthcare provider named by the patient within 30 days of   |
|              |              | -  | istration.  |
|              |              |  |   |
| (Sour        | ce: An       | nended a   | t 47 Ill. Reg, effective)   |
| `            |              |  |   |
| Section 1330 | .90 Re       | estoratio  | on of a Pharmacist License  |
|              |              |  |   |
| a)           | A ph         | armacist   | seeking restoration of a certificate of registration that has expired   |
| •            | for 5        | years or   | less shall have the license restored upon payment of all lapsed   |
|              | renev        | val fees 1   | required by Section 1330.20 and proof of 30 hours of CE continuing  |
|              | Section 1330 | (Source: An Section 1330.90 Retains a) A phonor of the section 5 | pharm for inf parent statem  4) The pl Adver provid  c) Recordkeepin  1) All rec years.  A)  B)  C)  D)  E)  F)  2) A pha vaccin 30 day Auton primat admin  (Source: Amended a  Section 1330.90 Restoration  a) A pharmacist for 5 years or |

| 299 |      |         |  |           | ficate of attendance or completion) in accordance with               |  |  |  |
|-----|------|---------|--|-----------|--|--|--|--|
| 300 |      | Section | on 1330.   | 100.      |  |  |  |  |
| 301 | 1. \ | A1      |  | 1-!       |  |  |  |  |
| 302 | b)   | -       |  | -         | g restoration of a certificate of registration that has been         |  |  |  |
| 303 |      |         |  |           | atus for 5 years or less shall have the license restored upon        |  |  |  |
| 304 |      |         | payment of the current renewal fee and proof of 30 hours of <u>CE continuing</u> |           |  |  |  |  |
| 305 |      |         |  |           | ficate of attendance or completion) in accordance with               |  |  |  |
| 306 |      | Section | on 1330.   | 100.      |  |  |  |  |
| 307 | `    | A 1     | ٠,   |           |  |  |  |  |
| 308 | c)   | -       |  | •         | g restoration of a certificate of registration after it has expired  |  |  |  |
| 309 |      |         | -  |           | active status for more than 5 years shall file an application, on    |  |  |  |
| 310 |      |         |  | •         | e Division, together with the fee required by Section 1330.20        |  |  |  |
| 311 |      | -       |  |           | s of <u>CE</u> continuing education (e.g., certificate of attendance |  |  |  |
| 312 |      | or cor  | npletion   | i) in acc | cordance with Section1330.100.                                       |  |  |  |
| 313 |      | 4.5     |  |           |  |  |  |  |
| 314 |      | 1)      | The pl   | harmaci   | ist shall also submit either:  |  |  |  |
| 315 |      |         |  |           |  |  |  |  |
| 316 |      |         | A)   |           | ication of active practice in another jurisdiction. Evidence         |  |  |  |
| 317 |      |         |  |           | nclude a statement from the appropriate board or licensing           |  |  |  |
| 318 |      |         |  |           | rity in the other jurisdiction that the registrant was authorized    |  |  |  |
| 319 |      |         |  | to pra    | ctice during the term of active practice; or                         |  |  |  |
| 320 |      |         |  |           |  |  |  |  |
| 321 |      |         | B)   |           | fidavit attesting to military service as specified in Section 12     |  |  |  |
| 322 |      |         |  |           | Act. The applicant restoring a license shall be excused from         |  |  |  |
| 323 |      |         |  | the pa    | yment of any lapsed fee or any restoration fees.                     |  |  |  |
| 324 |      |         |  |           |  |  |  |  |
| 325 |      | 2)      | A pha  | rmacist   | who is unable to submit proof of satisfaction of either              |  |  |  |
| 326 |      |         | subsec   | ction (c) | )(1)(A) or (B) shall submit proof of completion of:                  |  |  |  |
| 327 |      |         |  |           |  |  |  |  |
| 328 |      |         | A)   | 30 ho     | urs of <u>CE</u> <del>continuing education</del> ; and               |  |  |  |
| 329 |      |         |  |           |  |  |  |  |
| 330 |      |         | B)   | Either    | ••   |  |  |  |
| 331 |      |         |  |           |  |  |  |  |
| 332 |      |         |  | i)        | 600 hours of clinical practice under the supervision of a            |  |  |  |
| 333 |      |         |  |           | licensed pharmacist completed within 2 years prior to                |  |  |  |
| 334 |      |         |  |           | restoration; or  |  |  |  |
| 335 |      |         |  |           |  |  |  |  |
| 336 |      |         |  | ii)       | Successful completion of the North American Pharmacist               |  |  |  |
| 337 |      |         |  |           | Licensure Examination (NAPLEX)Pharmacist Assessment                  |  |  |  |
| 338 |      |         |  |           | for Remediation Evaluation (PARE) examination. To be                 |  |  |  |
| 339 |      |         |  |           | successful, an applicant must receive a passing score of 75          |  |  |  |
| 340 |      |         |  |           | on the NAPLEXan overall score of 80 or higher, as well as            |  |  |  |
|     |      |         |  |           |  |  |  |  |
|     |      |         |  |           |  |  |  |  |

| 341 |               |                                     | a minimum score of 75 in each of the 3 content areas on the                   |  |  |  |  |
|-----|---------------|-------------------------------------|---|--|--|--|--|
| 342 |               |                                     | PARE examination.   |  |  |  |  |
| 343 |               |                                     |   |  |  |  |  |
| 344 |               | 3)                                  | The course work or clinical training described in subsections (c)(2)(A) and   |  |  |  |  |
| 345 |               |                                     | (c)(2)(B)(i) must have the prior approval of the Board.                       |  |  |  |  |
| 346 |               |                                     |   |  |  |  |  |
| 347 | d)            |                                     | the accuracy of any submitted documentation, or the relevance or              |  |  |  |  |
| 348 |               |                                     | ency of the course work or experience, is questioned by the Division          |  |  |  |  |
| 349 |               |                                     | e of lack of information, discrepancies or conflicts in information given, or |  |  |  |  |
| 350 |               | a need                              | for clarification, the registrant will be requested to:                       |  |  |  |  |
| 351 |               |                                     |   |  |  |  |  |
| 352 |               | 1)                                  | Provide information as may be necessary; and/or                               |  |  |  |  |
| 353 |               |                                     |   |  |  |  |  |
| 354 |               | 2)                                  | Appear for an interview before the Board to explain the relevance or          |  |  |  |  |
| 355 |               |                                     | sufficiency, clarify information given, or clear up any discrepancies in      |  |  |  |  |
| 356 |               |                                     | information.  |  |  |  |  |
| 357 |               |                                     |   |  |  |  |  |
| 358 | (Source       | e: Ame                              | ended at 47 Ill. Reg, effective)  |  |  |  |  |
| 359 |               |                                     |   |  |  |  |  |
| 360 | Section 1330. | 100 Co                              | ontinuing Education ("CE")  |  |  |  |  |
| 361 |               |                                     |   |  |  |  |  |
| 362 | a)            | CEContinuing Education Requirements |   |  |  |  |  |
| 363 |               |                                     |   |  |  |  |  |
| 364 |               | 1)                                  | Each person who applies for renewal of a license as a pharmacist shall        |  |  |  |  |
| 365 |               |                                     | complete 30 hours of continuing education (CE) during the 24 months           |  |  |  |  |
| 366 |               |                                     | preceding the expiration date of the license, in accordance with Section 12   |  |  |  |  |
| 367 |               |                                     | of the Act.   |  |  |  |  |
| 368 |               |                                     |   |  |  |  |  |
| 369 |               | 2)                                  | A renewal applicant is not required to comply with CE requirements for        |  |  |  |  |
| 370 |               |                                     | the first renewal after original licensure.                                   |  |  |  |  |
| 371 | • .           |                                     | 1070  |  |  |  |  |
| 372 | b)            | Appro                               | ved CEContinuing Education  |  |  |  |  |
| 373 |               | 4.5                                 |   |  |  |  |  |
| 374 |               | 1)                                  | CE credit shall be based upon the completion of courses offered by            |  |  |  |  |
| 375 |               |                                     | providers approved by the Accreditation Council for Pharmacy Education.       |  |  |  |  |
| 376 |               |                                     | These courses may be completed outside the State of Illinois.                 |  |  |  |  |
| 377 |               | 2)                                  |   |  |  |  |  |
| 378 |               | 2)                                  | Undergraduate Coursework  |  |  |  |  |
| 379 |               |                                     |   |  |  |  |  |
| 380 |               |                                     | A) Undergraduate coursework taken after completion of a first                 |  |  |  |  |
| 381 |               |                                     | professional degree in pharmacy through a recognized college or               |  |  |  |  |
| 382 |               |                                     | approved school of pharmacy (in accordance with Section                       |  |  |  |  |
| 383 |               |                                     | 1330.300 of this Part) may be used to fulfill the CE requirement if:          |  |  |  |  |
|     |               |                                     |   |  |  |  |  |

| 384                |    |  |               |  |  |
|--------------------|----|--|---------------|--|--|
| 385                |    | i) Evidence of course completion through an official                         |               |  |  |
| 386                |    | transcript and other documentation (e.g., certificate of                     | <b>:</b><br>- |  |  |
| 387                |    | completion or degree) of the university or college is                        |               |  |  |
| 388                |    | submitted that indicates the number of course content                        | hours         |  |  |
| 389                |    | completed; and   |               |  |  |
| 390                |    |  |               |  |  |
| 391                |    | ii) These courses are completed for college credit.                          |               |  |  |
| 392                |    |  |               |  |  |
| 393                |    | B) CE credit will be earned for each undergraduate course compl              | leted.        |  |  |
| 394                |    | One semester hour is equivalent to 15 CEcontinuing education                 | <del>n</del>  |  |  |
| 395                |    | hours, and one quarter hour is equivalent to 10 CEcontinuing                 |               |  |  |
| 396                |    | education hours.   |               |  |  |
| 397                |    |  |               |  |  |
| 398                | c) | Certification of CE Requirements   |               |  |  |
| 399                | ,  | 1  |               |  |  |
| 400                |    | 1) Each renewal applicant shall certify on the renewal application full      |               |  |  |
| 401                |    | compliance with CE requirements set forth in subsection (a).                 |               |  |  |
| 402                |    | (.,)   |               |  |  |
| 403                |    | 2) The Division may require additional evidence demonstrating compliant      | ance          |  |  |
| 404                |    | with the CE requirements. It is the responsibility of each renewal           | 41100         |  |  |
| 405                |    | applicant to retain or otherwise produce evidence of the compliance (        | (e.g          |  |  |
| 406                |    | certificate of attendance or completion). Evidence shall be required in      | _             |  |  |
| 407                |    | context of the Division's random audit in accordance with Section 12         |               |  |  |
| 408                |    | the Act.   | , 01          |  |  |
| 409                |    | the Act.   |               |  |  |
| 410                | d) | The same CE hours cannot be used to fulfill the CE requirement for more that | an            |  |  |
| 411                | u) | one renewal period.  |               |  |  |
| 412                |    | one renewal period.  |               |  |  |
| 413                | ۵) | Waiver of CE Requirements  |               |  |  |
| 413<br>414         | e) | waiver of CE Requirements  |               |  |  |
| 414<br>415         |    | 1) Any renewal applicant seeking renewal of a license without having for     | 5111xz        |  |  |
| 41 <i>5</i><br>416 |    | complied with these CE requirements shall file with the Division a           | ully          |  |  |
|                    |    |  | forth         |  |  |
| 417                |    | renewal application, along with the required fee, a statement setting f      |               |  |  |
| 418                |    | the facts concerning noncompliance and a request for waiver of the C         |               |  |  |
| 419                |    | requirements on the basis of these facts. A request for waiver shall b       | e             |  |  |
| 420                |    | made prior to the renewal date. If the Division, upon the written            |               |  |  |
| 421                |    | recommendation of the Board, finds from the affidavit or any other           |               |  |  |
| 422                |    | evidence submitted that good cause has been shown for granting a wa          |               |  |  |
| 423                |    | the Division shall waive enforcement of the CE requirements for the          |               |  |  |
| 424                |    | renewal period for which the applicant has applied.                          |               |  |  |
| 425                |    |  |               |  |  |
| 426                |    | 2) Good cause shall be defined as an inability to fulfill the CE requirem    | ents          |  |  |

| 127             | during                       | g the ap  | oplicable period because of:  |
|-----------------|------------------------------|-----------|---|
| 128             | A \                          | E 11 .    |   |
| 129             | A)                           |           | time service in the armed forces of the United States of  |
| 130             |                              | Amer      | rica during the applicable period; or   |
| 431             |                              |           |   |
| 132             | B)                           |           | me hardship, which shall be determined on an individual   |
| 133             |                              | basis     | by the Board and shall be limited to documentation of:  |
| 134             |                              |           |   |
| 435             |                              | i)        | An incapacitating illness, documented by a currently  |
| 436             |                              |           | licensed physician; or  |
| 137             |                              |           |   |
| 138             |                              | ii)       | Physical inability to travel to the sites of approved   |
| 139             |                              |           | programs, as documented by a currently licensed physician;  |
| 440             |                              |           | or  |
| <b>141</b>      |                              |           |   |
| 142             |                              | iii)      | Any other similar extenuating circumstances (e.g., illness  |
| 143             |                              |           | of family member).  |
| 144             |                              |           | ·   |
| 145             | 3) An in                     | terview   | before the Board with respect to a request for waiver   |
| 146             |                              |           | granted-only if the interview is requested at the time the  |
| 147             | •                            |           | ne waiver is filed with the Division. The renewal applicant   |
| 148             | <u>-</u>                     |           | waiver shall be given at least 20 days written notice of the  |
| 149             | <u>=</u>                     | _         | d place of the interview by certified mail, or email return   |
| 450             |                              | ot reque  | - ·   |
| 451             |                              | 1         |   |
| <del>1</del> 52 | 4) Any r                     | enewal    | applicant who submits a request for waiver pursuant to  |
| 453             | ,                            |           | e)(1) shall be deemed to be in good standing until the final  |
| <b>154</b>      |                              |           | ision on the application has been made.   |
| <del>1</del> 55 |                              |           |   |
| 456             | (Source: Amended a           | at 47 Ill | . Reg, effective)   |
| 157             | (                            |           | ,   |
| 158             | SU                           | JBPAR     | T B: PHARMACY TECHNICIAN  |
| 159             | ~                            |           |   |
| 460             | Section 1330.230 Continui    | ing Edı   | ucation ("CE") for Certified Pharmacy Technicians   |
| 461             | Section 10001200 Continu     | ing But   | determine The man man of the man man of the |
| 162             | <u>a)</u> <u>CE Requirem</u> | nents     |   |
| 163             | <u>uj</u> <u>el Requiren</u> | icits     |   |
| 164             | <u>1)</u> Numb               | er of H   | Iours of CE Required  |
| 165             | 1)                           | <u> </u>  | iodis of CL Required  |
| 166             | <u>A)</u>                    | Each      | person who applies for renewal of a license as a certified  |
| <del>1</del> 67 | <u>A)</u>                    |           | nacy technician shall complete 10 hours of CE during the 12   |
| 468             |                              |           | hs preceding the expiration date of the license, in accordance  |
| +08<br>469      |                              |           | Section 9.5 of the Act.   |
| TUフ             |                              | WILL      | Section 7.3 of the Act.   |

| 470<br>471<br>472                      |           |           | <u>B)</u>                    | A renewal applicant is not required to comply with CE requirements for the first renewal after original licensure.   |  |
|--|-----------|-----------|------------------------------|--|--|
| 173<br>174                             |           | <u>2)</u> | Requi                        | red Topics for CE  |  |
| 475<br>476<br>477                      |           |           | <u>A)</u>                    | At least one hour of continuing pharmacy education must be on the subject of pharmacy laws, pharmacy rules and ethics;   |  |
| 478<br>479<br>480                      |           |           | <u>B)</u>                    | At least one hour of continuing pharmacy education must be on the subject of patient safety; and   |  |
| 481<br>482                             |           |           | <u>C)</u>                    | Any other applicable CE requirement per 68 Ill. Adm. Code 1130.  |  |
| 183<br>184<br>185                      | <u>b)</u> | Appro     | ved CE                       |  |  |
| 486<br>487<br>488<br>489               |           | <u>1)</u> | Accree nation                | ompletion of courses offered by providers approved by the ditation Council on Pharmacy Education or another standardized ally approved education program approved by the Department, may be completed outside the State of Illinois.   |  |
| 190<br>191<br>192<br>193               |           | <u>2)</u> | mainta                       | narmacist-in-charge and the certified pharmacy technician must ain records showing proof of training that constituted the pharmacy cian's CE.  |  |
| 194<br>195                             | <u>c)</u> | Certif    | ification of CE Requirements |  |  |
| 196<br>197<br>198                      |           | <u>1)</u> |                              | renewal applicant shall certify on the renewal application full iance with CE requirements set forth in this Part.   |  |
| 499<br>500<br>501<br>502<br>503<br>504 |           | 2)        | with the to reta             | ivision may require additional evidence demonstrating compliance ne CE requirements. It is the responsibility of each renewal applicant in or otherwise produce evidence of the compliance (e.g., certificate ndance or completion). Evidence shall be required in the context of vision's random audit in accordance with Section 9.5 of the Act. |  |
| 505<br>506<br>507                      | <u>d)</u> | ·         | ame CE<br>newal p            | hours cannot be used to fulfill the CE requirement for more than beriod.   |  |
| 508<br>509                             | <u>e)</u> | Waive     | Waiver of CE Requirements    |  |  |
| 510<br>511<br>512                      |           | <u>1)</u> |                              | enewal applicant seeking to renew their license without having fully ied with these CE requirements shall file with the Division a   |  |
|  |           |           |                              |  |  |

| 513                    |              |                         | ication, along with the required fee, a statement setting forth |
|------------------------|--------------|-------------------------|---|
| 514                    |              |                         | cerning noncompliance and a request for waiver of the CE        |
| 515                    |              |                         | with facts explaining the basis of the request. A request for   |
| 516                    |              |                         | be made prior to the renewal date. If the Division, upon the    |
| 517                    |              | •                       | nmendation of the Board, finds from the affidavit or any other  |
| 518                    |              | evidence sub            | mitted that good cause has been shown for granting a waiver,    |
| 519                    |              | the Division            | shall waive enforcement of the CE requirements for the          |
| 520                    |              | renewal perio           | od for which the applicant has applied.                         |
| 521                    |              |                         |   |
| 522                    | <u>2)</u>    | Good cause s            | shall be defined as an inability to fulfill the CE requirements |
| 523                    |              | during the ap           | pplicable period because of:                                    |
| 524                    |              |                         |   |
| 525                    |              | <u>A)</u> <u>Full-t</u> | time service in the armed forces of the United States of        |
| 526                    |              | Amer                    | rica during the applicable period; or                           |
| 527                    |              |                         |   |
| 528                    |              | B) Extre                | me hardship, which shall be determined on an individual         |
| 529                    |              |                         | by the Board and shall be limited to documentation of:          |
| 530                    |              |                         |   |
| 531                    |              | <u>i)</u>               | An incapacitating illness, documented by a currently            |
| 532                    |              | =                       | licensed physician;   |
| 533                    |              |                         |   |
| 534                    |              | <u>ii)</u>              | Physical inability to travel to the sites of approved           |
| 535                    |              | <u> </u>                | programs, as documented by a currently licensed physician:      |
| 536                    |              |                         | or  |
| 537                    |              |                         | <u>01</u>   |
| 538                    |              | iii)                    | Any other similar extenuating circumstances (e.g., illness      |
| 539                    |              | <u>111)</u>             | of a family member).  |
| 540                    |              |                         | of a family member).  |
| 541                    | <u>3)</u>    | Δn interview            | before the Board may be granted with respect to a request       |
| 542                    | <u>5)</u>    | •                       | the interview is requested at the time the request for the      |
| 543                    |              |                         | ed with the Division, and the Board determines that an          |
| 544<br>544             |              |                         | Il be necessary to consider the waiver request. The renewal     |
| 54 <del>4</del><br>545 |              |                         | uesting a waiver shall be given at least 20 days written notice |
| 545<br>546             |              |                         | •   |
|                        |              | or the date, th         | ime, and place of the interview by mail or email.               |
| 547                    | 4)           | A                       | and it could release the annual for received account to         |
| 548                    | <u>4)</u>    |                         | applicant who submits a request for waiver pursuant to          |
| 549                    |              |                         | e)(1) shall be deemed to be in good standing until the final    |
| 550                    |              | Division deci           | ision on the application has been made.                         |
| 551                    | (C           | 1 1 4 4 7 7 11 5        |   |
| 552                    | (Source: Add | ied at 47 III. Re       | eg, effective)  |
| 553                    |              | ~~                      | VDD A DEL C. DVI A DVI A CVOE                                   |
| 554                    |              | SU                      | JBPART C: PHARMACIST  |
| 555                    |              |                         |   |

### 556 **Section 1330.360 Pharmacy Residents** 557 558 A pharmacy resident participating in a nationally accredited residency program is exempt from 559 Section 15.1(a) of the Act to the extent the provision conflicts with the requirements of the 560 nationally accredited residency program. 561 (Source: Added at 47 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_) 562 563 564 SUBPART E: TYPES OF PHARMACIES 565 Section 1330.500 Community Pharmacy Services 566 567 568 a) Pharmacies that engage in general or specialty community pharmacy practice and 569 are open to, or offer pharmacy service to, the general public shall, in addition to 570 any other requirements of the Act and this Part, comply with this Section. A 571 community pharmacy that, in addition to offering pharmacy services to the 572 general public, provides institutional services shall also comply with Section 573 1330.520. 574 575 Staffing of the Pharmacy b) 576 577 1) Whenever the hours of the pharmacy differ from those of the establishment in which the pharmacy is located, the schedule during which 578 579 pharmacy services are provided shall be conspicuously displayed. 580 581 2) Whenever a pharmacy is open and a pharmacist is not present and 582 available to provide pharmacy services, a sign stating that situation shall 583 be conspicuously displayed. 584 585 No prescription may be dispensed when a pharmacist is not physically 3) 586 present in the establishment and on duty. 587 588 c) Recordkeeping Requirements for Dispensing Prescription Drugs 589 590 1) For every prescription dispensed, the prescription record shall contain the 591 name, initials or other unique identifier of the pharmacist who dispenses 592 the prescription drugs. No prescription may be dispensed after 15 monthsone year from the date of the original issuance of the prescription 593 594 by the prescriber. 595 596 2) Whenever a prescription is dispensed by a registered pharmacy technician or certified pharmacy technician under the supervision of a pharmacist, the 597 598 prescription record shall contain the names, initials or other unique

| 599        |    |   | of both the supervising pharmacist and the registered pharmacy      |  |  |  |  |
|------------|----|---|---|--|--|--|--|
| 600        |    | technician or certified pharmacy technician who dispenses the |   |  |  |  |  |
| 601        |    | prescription  | on.   |  |  |  |  |
| 602        |    |   |   |  |  |  |  |
| 603        | 3) | Refilling a   | a Prescription  |  |  |  |  |
| 604        |    |   |   |  |  |  |  |
| 605        |    | A) Ea   | ch refilling of a prescription shall be entered on the prescription |  |  |  |  |
| 606        |    | or  | on another appropriate, uniformly maintained, readily               |  |  |  |  |
| 607        |    | ret   | rievable record that indicates, by the number of the prescription,  |  |  |  |  |
| 608        |    | the   | e following information:  |  |  |  |  |
| 609        |    |   |   |  |  |  |  |
| 610        |    | i)  | The name and dosage form of the drug;                               |  |  |  |  |
| 611        |    | ŕ   |   |  |  |  |  |
| 612        |    | ii)   | The date of each refilling;   |  |  |  |  |
| 613        |    | ,   | <i>2</i> ,  |  |  |  |  |
| 614        |    | iii)  | The quantity dispensed;   |  |  |  |  |
| 615        |    | ,   |   |  |  |  |  |
| 616        |    | iv)   | The name or initials of the pharmacist and the pharmacy             |  |  |  |  |
| 617        |    |   | technician, if applicable, in each refilling; and                   |  |  |  |  |
| 618        |    |   | ······································                              |  |  |  |  |
| 619        |    | v)  | The total number of refills remaining for the prescription.         |  |  |  |  |
| 620        |    | .,  |   |  |  |  |  |
| 621        |    | B) If   | the pharmacist does not otherwise indicate in a uniformly           |  |  |  |  |
| 622        |    | *   | aintained record, he or she shall be deemed to have dispensed a     |  |  |  |  |
| 623        |    |   | fill for the full face amount of the prescription.                  |  |  |  |  |
| 624        |    | 101   | in for the fair face amount of the prescription.                    |  |  |  |  |
| 625        | 4) | Presentati  | on of a written prescription copy or prescription label shall be    |  |  |  |  |
| 626        | '/ |   | nation purposes only and has no legal status as a valid             |  |  |  |  |
| 627        |    |   | on order. The recipient pharmacist of the copy or prescription      |  |  |  |  |
| 628        |    | • •   | contact the prescribing practitioner to obtain a new prescription   |  |  |  |  |
| 629        |    | order.  | contact the preserioning practitioner to obtain a new presemption   |  |  |  |  |
| 630        |    | oruci.  |   |  |  |  |  |
| 631        | 5) | Copies of   | prescriptions given to an ultimate consumer shall be marked         |  |  |  |  |
| 632        | 3) | -   | rmation Purposes Only".   |  |  |  |  |
| 633        |    | 1 Of Illion   | mation i diposes only.  |  |  |  |  |
|            | 6) | Cubicat to  | Section 18 of the Act, any information required to be kept          |  |  |  |  |
| 634<br>635 | 6) | •   | · · · · · · · · · · · · · · · · · · ·                               |  |  |  |  |
| 635        |    | -   | o this Section may be recorded and stored in a computerized         |  |  |  |  |
| 636<br>637 |    | -   | utical information system that meets the standards of               |  |  |  |  |
| 637        |    | -   | nce stated in the regulations of the Drug Enforcement               |  |  |  |  |
| 638        |    |   | ration (21 CFR 1306; 2014), except as provided in subsection        |  |  |  |  |
| 639        |    | (c)(/), and   | I shall include the capability to:                                  |  |  |  |  |
| 640        |    |   |   |  |  |  |  |
|            |    |   |   |  |  |  |  |

| 541        |    | A)       |          | ve the original prescription order information for those   |
|------------|----|----------|----------|--|
| 542        |    |          | prescr   | iption orders currently authorized for refilling;  |
| 543<br>544 |    | D)       | Datria   | ve the augment prescription orders including at a minimum  |
| 545        |    | B)       |          | ve the current prescription orders, including, at a minimum,   |
| 546        |    |          |          | of drug, date of refill, quantity dispensed, name and  |
| 547        |    |          |          | ication code of the manufacturer in the case of a generically  |
| 548        |    |          |          | n prescription or a generic interchange, name or initials of spensing pharmacist and technician for each refill, and the |
| 549        |    |          |          | umber of refills dispensed to date;  |
| 550        |    |          | totai ii | umber of ferms dispensed to date,  |
| 551        |    | C)       | Supply   | y documentation of refill information entered by the   |
| 552        |    | C)       |          | acist using the system through a hard copy printout of each  |
| 553        |    |          | -        | refill data that has been verified for correctness. This printout  |
| 554        |    |          | •        | nclude for each prescription filled at least the following   |
| 555        |    |          | inform   | <u> </u>   |
| 556        |    |          | шош      | iation.  |
| 657        |    |          | i)       | The name and dosage form of the drug;  |
| 558        |    |          | 1)       | The name and dosage form of the drug,  |
| 559        |    |          | ii)      | The date of each refilling;  |
| 560        |    |          | 11)      | The date of each ferning,  |
| 561        |    |          | iii)     | The quantity dispensed;  |
| 562        |    |          | 111)     | The quantity dispensed,  |
| 563        |    |          | iv)      | The name or initials of the pharmacist in each refilling and   |
| 564        |    |          | 11)      | the pharmacy technician, if applicable;  |
| 565        |    |          |          | the pharmacy teemmeran, it approaches,   |
| 566        |    |          | v)       | The patient's name;  |
| 567        |    |          | • /      | The purious summer,  |
| 568        |    |          | vi)      | The prescriber's name; and   |
| 569        |    |          |          | · ·  |
| 570        |    |          | vii)     | The prescription number for the prescription.  |
| 571        |    |          | ,        |  |
| 572        | 7) | In lieu  | of the   | printout required by subsection (c)(6), the pharmacy shall   |
| 573        |    | mainta   | in a bo  | und log book, or separate file, in which each individual   |
| 574        |    |          |          | volved in the dispensing shall sign a statement each day,  |
| 575        |    | attestir | ng to th | e fact that the refill information entered into the computer   |
| 576        |    | that da  | y has b  | een reviewed by him/her and is correct as shown. The book  |
| 577        |    | or file  | must be  | e maintained at the pharmacy employing the system for a  |
| 578        |    |          |          | ars after the date of dispensing the appropriately authorized  |
| 579        |    | refill.  | -        |  |
| 580        |    |          |          |  |
| 581        | 8) | All ref  | ill data | shall be maintained by the pharmacy on the premises for 5  |
| 582        |    | years,   | in acco  | rdance with Section 18 of the Act. The pharmacy shall have   |
| 583        |    | the app  | propriat | e equipment on the premises to provide readily retrievable   |
|            |    |          |          |  |

684 information in the course of an on-site inspection. A hard copy printout 685 shall be provided to the Division, upon request, within 48 hours. 686 687 d) Any drug that is dispensed pursuant to prescription, other than vaccinations administered in the pharmacy, shall have affixed to its container a label as 688 689 provided in Section 22 of the Act. 690 691 e) No person shall establish or move to a new location any pharmacy unless the 692 pharmacy is licensed with the Division and has on file with the Division a verified 693 statement that: 694 695 1) The pharmacy is or will be engaged in the practice of pharmacy; and 696 697 2) The pharmacy will have in stock and will maintain sufficient prescription 698 drugs and materials to protect the public it serves within 30 days after 699 opening of the pharmacy. 700 701 f) Pharmacies have a duty to deliver lawfully prescribed drugs to patients and to 702 distribute nonprescription drugs approved by the U.S. Food and Drug 703 Administration for restricted distribution by pharmacies, or to substitute a generic 704 drug as permitted in Section 25 of the Act in a timely manner, or to contact the 705 prescriber to obtain authorization to dispense a different drug that produces a 706 similar clinical effect in a timely manner, except for the following or substantially 707 similar circumstances: 708 709 1) When, in the pharmacist's professional judgment, after screening for 710 potential drug therapy problems due to therapeutic duplication, drug-711 disease contraindications, drug-drug interactions (including, but not limited to, serious interactions with nonprescription or over-the-counter 712 713 drugs), drug-food interactions, incorrect drug dosage or duration of drug 714 treatment, drug-allergy interactions, or clinical abuse or misuse, pursuant 715 to Section 3(aa) of the Act, she or he determines that the drug should not 716 be dispensed due to one of the foregoing clinical reasons; 717 718 2) National or State emergencies or guidelines affecting availability, usage or 719 supplies of drugs; 720 721 3) Lack of specialized equipment or expertise needed to safely produce, store 722 or dispense drugs, such as certain drug compounding or storage for 723 nuclear medicine; 724 725 4) Potentially fraudulent prescriptions; 726

| 727        |     | 5) Unavailability of drug; or  |
|------------|-----|--|
| 728        |     |  |
| 729        |     | 6) The drug is not typically carried in similar practice settings in the State.            |
| 730        | ,   |  |
| 731        | g)  | Nothing in this Section requires pharmacies to dispense a drug without payment             |
| 732        |     | of their usual and customary or contracted charge.   |
| 733        | 1.) | All whomes sice shall be required to reciptain the following comment recovers              |
| 734<br>735 | h)  | All pharmacies shall be required to maintain the following current resource                |
| 736        |     | materials, either in hard copy or electronic format:                                       |
| 730<br>737 |     | 1) Copies of the Act and this Part;  |
| 738        |     | 1) Copies of the Act and this I art,   |
| 739        |     | 2) The Illinois Controlled Substances Act and 77 Ill. Adm. Code 3100;                      |
| 740        |     | 2) The fillions controlled substances feet and 77 In. Fam. Code 3100,                      |
| 740<br>741 |     | 3) 21 CFR (Food and Drugs; 2014); and  |
| 742        |     | 3) 21 CTR (1 00d and 1514g), 2011), and  |
| 743        |     | 4) The Illinois Hypodermic Syringes and Needles Act [720 ILCS 635].                        |
| 744        |     | ,  |
| 745        | i)  | If the lawfully prescribed drug or nonprescription drug approved by the U.S. Food          |
| 746        | ,   | and Drug Administration for restricted distribution by pharmacies is not in stock          |
| 747        |     | or is otherwise unavailable, or the prescription cannot be filled pursuant to              |
| 748        |     | subsection $(f)(1)$ or $(f)(6)$ , the pharmacy shall provide the patient or agent a timely |
| 749        |     | alternative for appropriate therapy that, consistent with customary pharmacy               |
| 750        |     | practice, may include obtaining the drug. These alternatives include but are not           |
| 751        |     | limited to:  |
| 752        |     |  |
| 753        |     | 1) Contact the prescriber to address concerns such as those identified in                  |
| 754        |     | subsection (f)(1);   |
| 755        |     |  |
| 756        |     | 2) If requested by the patient or his or her agent, return unfilled lawful                 |
| 757        |     | prescriptions to the patient or agent; or  |
| 758        |     |  |
| 759        |     | 3) If requested by the patient or his or her agent, communicate or transmit, as            |
| 760        |     | permitted by law, the original prescription information to a pharmacy of                   |
| 761        |     | the patient's choice that will fill the prescription in a timely manner.                   |
| 762        | • ` |  |
| 763        | j)  | Any mail order pharmacy that provides services in Illinois shall provide, during           |
| 764<br>765 |     | its regular hours of operation, but not less than 6 days per week for a minimum of         |
| 765        |     | 40 hours per week, a toll-free telephone service to facilitate communication               |
| 766<br>767 |     | between patients in this State and a pharmacist retained by the mail order                 |
| 767<br>768 |     | pharmacy who has access to the patient's records. The toll free number must be             |
| 768<br>769 |     | disclosed on the label affixed to each container of drugs dispensed to residents of        |
| / リンプ      |     | the State.   |

| 770        |               |   |
|------------|---------------|---|
| 771        | k)            | Engaging in or permitting any of the following shall constitute grounds for         |
| 772        |               | discipline or other enforcement actions:  |
| 773        |               |   |
| 774<br>775 |               | 1) Intentionally destroying unfilled lawful prescriptions;                          |
| 776        |               | 2) Refusing to return unfilled lawful prescriptions;                                |
| 777        |               |   |
| 778        |               | 3) Violating a patient's privacy;   |
| 779        |               |   |
| 780        |               | 4) Discriminating against patients or their agents in a manner prohibited by        |
| 781        |               | State or federal laws;  |
| 782        |               |   |
| 783        |               | 5) Intimidating or harassing a patient; or  |
| 784        |               |   |
| 785        |               | 6) Failing to comply with the requirements of this Section.                         |
| 786        | <b>49</b>     |   |
| 787        | (Source       | ee: Amended at 47 Ill. Reg, effective)  |
| 788        | G             | 710 T. L. L   |
| 789<br>790 | Section 1330. | 510 Telepharmacy  |
| 790<br>791 | ٥)            | Telepharmacy shall be limited to the types of operations described in this Section. |
| 791<br>792 | a)            | Each site where such operations occur shall be a separately licensed pharmacy.      |
| 793        |               | Home pharmacies that are located outside of Illinois must be licensed as a          |
| 794        |               | nonresident pharmacy. Nonresident pharmacies shall abide by all Illinois laws and   |
| 795        |               | rules when filling prescriptions for Illinois residents, except that the dispensing |
| 796        |               | pharmacist and the pharmacist-in-charge shall not be required to be licensed in     |
| 797        |               | Illinois, except as otherwise provided in this Part.                                |
| 798        |               |   |
| 799        | b)            | Remote Dispensing Site  |
| 800        | ,             |   |
| 801        |               | 1) Written prescriptions presented to the remote dispensing site shall be           |
| 802        |               | scanned into the electronic data processing equipment to ensure initial             |
| 803        |               | dispensing and each refill and the original prescription may be viewed on           |
| 804        |               | the monitor at both the remote dispensing site and home pharmacy site.              |
| 805        |               | Unless otherwise provided by federal law, all written prescriptions shall be        |
| 806        |               | delivered to the home pharmacy for filing within 72 hours. Records shall            |
| 807        |               | be maintained at the remote dispensing site the home pharmacy in files              |
| 808        |               | separate from the home pharmacy files.  |
| 809        |               |   |
| 810        |               | 2) A remote site is considered to be under the supervision of the pharmacist-       |
| 811        |               | in-charge of the home pharmacy. <u>Each home pharmacy may supervise no</u>          |
| 812        |               | more than 3 remote sites that are simultaneously open.                              |
|            |               |   |

- 3) The remote site shall use its home pharmacy and pharmacy management system.
  - A) The system shall assign consecutive prescription numbers.
  - B) All records must be maintained at the home pharmacy.
  - Prescriptions dispensed at the remote site shall be distinguishable from those dispensed from the home pharmacy.
  - **CD**) Daily reports must be separated for the home and remote site.
- 4) A pharmacist at the home pharmacy must verify each prescription before it leaves the remote site.
  - A) Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.
  - B) A pharmacist shall electronically compare via video link the stock bottle, drug dispensed, the strength and its beyond use date. The entire label must be checked for accuracy on the video link.
  - C) The remote dispensing site shall utilize a barcode system that prints the barcode of the stock bottle on the label of the dispensed drug. If the stock bottle does not have a barcode, the pharmacy shall create one. The technician shall scan both the stock bottle and the label of the dispensed drug to verify that the drug dispensed is the same as the drug in the stock bottle for each prescription dispensed.
  - D) A pharmacy may utilize a different electronic verification system that accomplishes the same purpose after review and approval of the Division.
- Counseling must be done by a pharmacist via video link and audio link before the drug or medical device is released. pursuant to Section 700 The pharmacist providing counseling, pursuant to this subsection, must be employed or contracted by the home pharmacy or by a pharmacy contracted with the home pharmacy and have access to all relevant patient information maintained by the home pharmacy.

| 855 |    | 6)             | A pharmacist-in-charge or his or her designated pharmacist must complete    |
|-----|----|----------------|---|
| 856 |    |                | monthly inspections of the remote site. Inspection criteria must be         |
| 857 |    |                | included in the policies and procedures for the site. The inspection report |
| 858 |    |                | must be available on site for pharmacy investigator inspection.             |
| 859 |    |                |   |
| 860 |    | 7)             | Controlled substances shall be kept at the remote site in accordance with   |
| 861 |    |                | the Act and this Part. All records must be stored at the home pharmacy      |
| 862 |    |                | and at the remote site.   |
| 863 |    |                |   |
| 864 |    | 8)             | There shall be a working computer link, video link and audio link to a      |
| 865 |    |                | pharmacist at a home pharmacy whenever the prescription area is open to     |
| 866 |    |                | the public. The communication link must be checked daily and the remote     |
| 867 |    |                | site pharmacy must be closed if the link malfunctions, unless a pharmacist  |
| 868 |    |                | is physically present at the remote site.                                   |
| 869 |    |                |   |
| 870 |    |                | A) The pharmacy technician located at the remote dispensing site            |
| 871 |    |                | must have one year of experience and be registered as a certified           |
| 872 |    |                | pharmacy technician, or be a student pharmacist.                            |
| 873 |    |                |   |
| 874 |    |                | B) New prescriptions received at the remote dispensing site may be          |
| 875 |    |                | entered into the remote computer system with all verification,              |
| 876 |    |                | interaction, checking and profile review by the pharmacist at the           |
| 877 |    |                | home pharmacy.  |
| 878 |    |                |   |
| 879 |    |                | C) Each pharmacist at the home pharmacy may electronically                  |
| 880 |    |                | supervise no more than 3 remote sites that are simultaneously               |
| 881 |    |                | open.   |
| 882 |    |                |   |
| 883 |    | 9)             | The facility must have a sign clearly identifying it as a remote dispensing |
| 884 |    |                | site.   |
| 885 |    |                |   |
| 886 |    | <del>10)</del> | Security of filled prescriptions must be maintained by storing them in a    |
| 887 |    |                | separate lock drawer or cabinet.  |
| 888 |    |                |   |
| 889 |    | <u>10</u> 11)  | The facility shall have an area for patient consultation, exclusive of any  |
| 890 |    |                | waiting area.   |
| 891 |    |                |   |
| 892 | c) | Remo           | te Consultation Site  |
| 893 |    |                |   |
| 894 |    | 1)             | These sites have no prescription inventory.                                 |
| 895 |    |                |   |
| 896 |    | 2)             | Only filled prescriptions, filled at the home pharmacy, with final patient  |
| 897 |    |                | labeling attached are allowed at these sites.                               |
|     |    |                |   |

| 898 |    |      |  |  |  |  |  |  |
|-----|----|------|--|--|--|--|--|--|
| 899 |    | 3)   | These  | e sites must be staffed with a pharmacy technician or certified  |  |  |  |  |
| 900 |    |      | pharmacy technician who has the knowledge necessary to use compute |  |  |  |  |  |
| 901 |    |      | audio  | /video link for dispensing and consultation to occur. Pharmacist and   |  |  |  |  |
| 902 |    |      |  | nacy technician initials or unique identifiers must appear on the  |  |  |  |  |
| 903 |    |      | -  | ription record and the prescription label.   |  |  |  |  |
| 904 |    |      | 1  |  |  |  |  |  |
| 905 |    | 4)   | Writt  | en prescriptions may be received at a remote consultation site. All  |  |  |  |  |
| 906 |    | ,    |  | en prescriptions presented at a remote consultation site shall be  |  |  |  |  |
| 907 |    |      |  | ered to the home pharmacy within 72 hours.   |  |  |  |  |
| 908 |    |      |  | 1  |  |  |  |  |
| 909 |    | 5)   | Secur  | rity of filled prescriptions must be maintained by storing them in a   |  |  |  |  |
| 910 |    | ,    |  | ate lock drawer or cabinet.  |  |  |  |  |
| 911 |    |      |  |  |  |  |  |  |
| 912 |    | 6)   | Reco   | rdkeeping shall be conducted by the pharmacist (time/date) when  |  |  |  |  |
| 913 |    | -/   |  | nsing and counseling occurred.   |  |  |  |  |
| 914 |    |      | P  |  |  |  |  |  |
| 915 |    | 7)   | The f  | acility shall have a room for patient consultation exclusive of any  |  |  |  |  |
| 916 |    | - /  |  | ng area.   |  |  |  |  |
| 917 |    |      |  |  |  |  |  |  |
| 918 |    | 8)   | The f  | acility must have a sign clearly identifying it as a remote consultation   |  |  |  |  |
| 919 |    | - /  | site.  | , , , , , , , , , , , , ,  |  |  |  |  |
| 920 |    |      |  |  |  |  |  |  |
| 921 | d) | Auto | mated P  | Charmacy Systems (Section 22(b) of the Act)  |  |  |  |  |
| 922 | /  |      |  | and the grant of the control of the  |  |  |  |  |
| 923 |    | 1)   | Remo   | ote Automated Pharmacy Systems (RAPS)  |  |  |  |  |
| 924 |    | ,    |  | ,  |  |  |  |  |
| 925 |    |      | A)   | These devices shall maintain a prescription drug inventory that is   |  |  |  |  |
| 926 |    |      | ,  | controlled electronically by the home pharmacy or, when operated   |  |  |  |  |
| 927 |    |      |  | by a pharmacy contracted with the home pharmacy, by the  |  |  |  |  |
| 928 |    |      |  | contracted pharmacy, which shall be utilized to dispense patient   |  |  |  |  |
| 929 |    |      |  | specific prescriptions.  |  |  |  |  |
| 930 |    |      |  | 1 1 1  |  |  |  |  |
| 931 |    |      | B)   | These systems shall have prescription inventory, which must be   |  |  |  |  |
| 932 |    |      | -,   | secured in an automated pharmacy system and electronically   |  |  |  |  |
| 933 |    |      |  | connected to and controlled by the home pharmacy.  |  |  |  |  |
| 934 |    |      |  | T a significant to the significa |  |  |  |  |
| 935 |    |      | C)   | A pharmacist must approve all the prescription orders before they  |  |  |  |  |
| 936 |    |      | - /  | are released from the RAPS.  |  |  |  |  |
| 937 |    |      |  |  |  |  |  |  |
| 938 |    |      | D)   | Dispensing and counseling are performed by a pharmacist  |  |  |  |  |
| 939 |    |      | ,  | employed or contracted by the home pharmacy via audio and video  |  |  |  |  |
| 940 |    |      |  | link.  |  |  |  |  |
| -   |    |      |  |  |  |  |  |  |

- E) All filled <u>prescriptions prescription</u> must have a label that meets the requirements of the Act attached to the final drug container.
- F) The pharmacist-in-charge of the home pharmacy, or a designated registrant, shall conduct and complete monthly inspections of the RAPS. Inspection criteria must be included in the policies and procedures for the site. The report must be available to the pharmacy investigators when requested.
- G) The RAPS must be licensed with the Division as an automated pharmacy system and will be subject to random inspection by pharmacy investigators. Notwithstanding that the RAPS shall possess a license, the home pharmacy shall remain responsible for inventory control and billing. For purposes of random inspections, a pharmacist with access to the system must be available at the site within one hour, or as otherwise approved by the drug compliance investigator. In the event the Chief Pharmacy Coordinator determines that the RAPS poses a significant risk of patient harm, the RAPS must be disabled until such time as the pharmacist with access to the system is available to the site.
- H) Medication dispensed at the automated pharmacy system site may only be packaged by a licensed manufacturer or repackager, or prepackaged by a licensed pharmacy in compliance with this Section. Prepackaging must occur at the home pharmacy, a pharmacy sharing common ownership with the home pharmacy, or a pharmacy that has contracted with the home pharmacy to perform prepackaging services. The following requirements shall apply whenever medications are prepackaged by a pharmacy other than the home pharmacy:
  - i) The prepackaging pharmacy shall be licensed in Illinois as a resident or nonresident pharmacy.
  - ii) The prepackaging pharmacy shall share a common database with the home pharmacy, or have in place an electronic or manual process to ensure that both pharmacies have access to records to verify the identity, lot numbers and expiration dates of the prepackaged medications stocked in the RAPS.

|            | iii) The prepackaging pharmacy shall maintain appropriate   |
|------------|---|
|            | records to identify the responsible pharmacist who verified the accuracy of the prepackaged medication. |
|            | the decuracy of the propackaged medication.   |
| I)         | Written prescriptions may be received at ann RAPS. All written  |
| ,          | prescriptions presented to aan RAPS shall be scanned utilizing  |
|            | imaging technology that permits the reviewing pharmacist to   |
|            | determine its authenticity. The sufficiency of the technology shall                                     |
|            | be determined by the Department. If sufficient technology is not  |
|            | used, the written prescriptions must be delivered to the home   |
|            | pharmacy and reviewed by a pharmacist prior to being dispensed  |
|            | to the patient.   |
|            |   |
| 2) Kiosk   |   |
|            |   |
| A)         | A kiosk is a device that maintains individual patient prescription                                      |
|            | drugs that were verified and labeled at the home pharmacy.  |
|            |   |
| B)         | A home pharmacy may only use the kiosk with prior approval of a   |
|            | patient.  |
|            |   |
| <b>C</b> ) | A kiosk located on the same premises or campus of the home  |
|            | pharmacy shall operate under the same license as the home   |
|            | pharmacy. However, a kiosk must be licensed with the Division if  |
|            | it is not so located.   |
| <b>D</b> ) | A 1 ' 1 1 11  |
| D)         | A kiosk shall:  |
|            | i) When leasted on the same numices on communication  |
|            | i) When located on the same premises or campus as the   |
|            | pharmacy, inform a patient, if he or she is using the device  |
|            | when the pharmacy is open, that the patient may address   |
|            | questions and concerns regarding the prescription to a pharmacist at the pharmacy;                      |
|            | pharmacist at the pharmacy,   |
|            | ii) When not located on the same premises or campus as the  |
|            | pharmacy, inform a patient, if he is using the device when  |
|            | the pharmacy is closed, that he or she may immediately  |
|            | direct any questions and concerns regarding the   |
|            | prescription to a licensed pharmacist via a pharmacy  |
|            | provided audio/video link;  |
|            | provided dudio/ video illing,   |
|            | iii) Inform a patient that a prescription is not available to be  |
|            | delivered by the device if the pharmacist has determined  |
|            | ,   |
|            |   |

1026 that he or she desires to counsel the patient in person 1027 regarding the prescription. 1028 1029 3) A pharmacy may use an automated pharmacy system to deliver 1030 prescriptions to a patient when the device: 1031 1032 A) Is secured against a wall or floor; 1033 1034 B) Provides a method to identify the patient and delivers the prescription only to that patient or the patient's authorized agent; 1035 1036 1037 C) Has adequate security systems and procedures to prevent unauthorized access, to comply with federal and State regulations, 1038 1039 and to maintain patient confidentiality; 1040 1041 D) Records the time and date that the patient removed the prescription from the system. 1042 1043 1044 4) A licensed automated pharmacy system shall not be utilized by 1045 prescribers. Nothing in this Section shall prevent a prescriber from 1046 utilizing an automated pharmacy system in connection with his or her own 1047 dispensing. However, a prescriber may not utilize or access an automated 1048 pharmacy system licensed pursuant to this Section. 1049 1050 e) All pharmacists performing services in support of a remote dispensing site, 1051 remote consultation site, kiosk, or RAPS must display a copy or electronic image 1052 of their licenses at the remote site where they provide services, or shall otherwise make their license visible to the patient, and be licensed in this State, unless 1053 employed by a pharmacy licensed in Illinois as a nonresident pharmacy, in which 1054 1055 case, the pharmacist providing the services shall hold an active license as a 1056 pharmacist in the state in which the nonresident pharmacy is located and only the pharmacist-in-charge of the remote site must be licensed in Illinois. 1057 1058 1059 f) Each remote site must display a sign, easily viewable by the customer, that states: 1060 1061 The facility is a telepharmacy supervised by a pharmacist located at 1) 1062 (address); and 1063 1064 2) The pharmacist is required to talk to you, over an audio/visual link, each 1065 time you pick up a prescription. 1066 1067 No remote site may be open when the home pharmacy is closed, unless a g) 1068 pharmacist employed or contracted by the home pharmacy, or by a pharmacy

| 1069 |              | contra   | acted with the home pharmacy, is present at the remote site or is remotely      |  |  |  |  |  |
|------|--------------|--|---|--|--|--|--|--|
| 1070 |              | providing supervision and consultation as required under this Section. |   |  |  |  |  |  |
| 1071 |              | •  | 2   |  |  |  |  |  |
| 1072 | (Sour        | ce: Am   | nended at 47 Ill. Reg, effective)   |  |  |  |  |  |
| 1073 | ,            |  |   |  |  |  |  |  |
| 1074 | Section 1330 | .520 O   | offsite Institutional Pharmacy Services   |  |  |  |  |  |
| 1075 |              |  |   |  |  |  |  |  |
| 1076 | a)           | Pharn  | nacies that are not located in the facilities they serve and whose primary      |  |  |  |  |  |
| 1077 |              | purpo  | se is to provide services to patients or residents of facilities licensed under |  |  |  |  |  |
| 1078 |              | the N  | ursing Home Care Act, the Hospital Licensing Act, or the University of          |  |  |  |  |  |
| 1079 |              | Illinoi  | is Hospital Act, or the Illinois Department of Human Services, Division of      |  |  |  |  |  |
| 1080 |              | Subst  | ance Use Prevention and Recovery shall, in addition to any other                |  |  |  |  |  |
| 1081 |              | requir   | rements of the Act and this Part, comply with this Section.                     |  |  |  |  |  |
| 1082 |              |  |   |  |  |  |  |  |
| 1083 | b)           | Recor  | dkeeping Requirements for Dispensing Prescriptions or Orders                    |  |  |  |  |  |
| 1084 |              |  |   |  |  |  |  |  |
| 1085 |              | 1)   | Every prescription or order dispensed shall be documented with the name,        |  |  |  |  |  |
| 1086 |              |  | initials or other unique identifiers of the pharmacist (and pharmacy            |  |  |  |  |  |
| 1087 |              |  | technician if one is used) authorized to practice pharmacy under the            |  |  |  |  |  |
| 1088 |              |  | provisions of the Act who dispenses the prescription or order. For              |  |  |  |  |  |
| 1089 |              |  | purposes of the Act, an authorized person is:                                   |  |  |  |  |  |
| 1090 |              |  |   |  |  |  |  |  |
| 1091 |              |  | A) A pharmacist licensed in the State of Illinois; or                           |  |  |  |  |  |
| 1092 |              |  |   |  |  |  |  |  |
| 1093 |              |  | B) A-registered pharmacy technician, certified pharmacy technician or           |  |  |  |  |  |
| 1094 |              |  | student pharmacist under the supervision of a pharmacist.                       |  |  |  |  |  |
| 1095 |              |  |   |  |  |  |  |  |
| 1096 |              | 2)   | Each pharmacy must maintain records for 5 years that contains the               |  |  |  |  |  |
| 1097 |              |  | information in subsection (b)(3). This information shall be readily             |  |  |  |  |  |
| 1098 |              |  | retrievable and in a format that provides enforcement agents a concise,         |  |  |  |  |  |
| 1099 |              |  | accurate and comprehensive method of monitoring drug distribution via an        |  |  |  |  |  |
| 1100 |              |  | audit trail. This system may require 2 or more documents that, when read        |  |  |  |  |  |
| 1101 |              |  | together, will provide all the information required by federal (e.g., the       |  |  |  |  |  |
| 1102 |              |  | regulations of the Drug Enforcement Administration (21 CFR 1300 et              |  |  |  |  |  |
| 1103 |              |  | seq.; 2014)) and State (e.g., the Pharmacy Practice Act and the Illinois        |  |  |  |  |  |
| 1104 |              |  | Controlled Substances Act [720 ILCS 570]) statute.                              |  |  |  |  |  |
| 1105 |              |  |   |  |  |  |  |  |
| 1106 |              | 3)   | In addition to the recordkeeping requirements of subsection (b)(2), a           |  |  |  |  |  |
| 1107 |              |  | uniformly maintained, readily retrievable hard copy record or back-up           |  |  |  |  |  |
| 1108 |              |  | documentation of each prescription or order dispensed shall be maintained       |  |  |  |  |  |
| 1109 |              |  | by the pharmacy for 5 years and shall include:                                  |  |  |  |  |  |
| 1110 |              |  |   |  |  |  |  |  |
| 1111 |              |  | A) Name of resident:  |  |  |  |  |  |

| 1112 |    |   |   |  |  |
|------|----|---|---|--|--|
| 1113 |    | B)  | Date of order;  |  |  |
| 1114 |    |   |   |  |  |
| 1115 |    | C)  | Name, strength and dosage form of drug, or description of the             |  |  |
| 1116 |    |   | medical device ordered;   |  |  |
| 1117 |    |   |   |  |  |
| 1118 |    | D)  | Quantity dispensed (a separate record should be maintained when           |  |  |
| 1119 |    |   | the quantity billed differs from the quantity dispensed, e.g., unit       |  |  |
| 1120 |    |   | dose transfer systems);   |  |  |
| 1121 |    |   |   |  |  |
| 1122 |    | E)  | Directions for use;   |  |  |
| 1123 |    |   |   |  |  |
| 1124 |    | F)  | Quantity billed;  |  |  |
| 1125 |    |   |   |  |  |
| 1126 |    | G)  | Prescriber's name;  |  |  |
| 1127 |    | ,   |   |  |  |
| 1128 |    | H)  | Prescriber's signature and/or DEA number when required for                |  |  |
| 1129 |    | ŕ   | controlled substances; and  |  |  |
| 1130 |    |   | ,   |  |  |
| 1131 |    | I)  | The drug name and identification code or the manufacturer in case         |  |  |
| 1132 |    | ,   | of a generically ordered medication or a generic interchange.             |  |  |
| 1133 |    |   |   |  |  |
| 1134 | 4) | No pi   | rescription may be filled or refilled for a period in excess of <u>15</u> |  |  |
| 1135 | ŕ  | _   | hsone year from the date of the original issuance of the prescription     |  |  |
| 1136 |    |   | der by the prescriber.  |  |  |
| 1137 |    |   | •   |  |  |
| 1138 | 5) | Subject to Section 18 of the Act, any information required to be kept |   |  |  |
| 1139 | ŕ  | pursuant to this Section may be recorded and stored in a:             |   |  |  |
| 1140 |    | •   | •   |  |  |
| 1141 |    | A)  | computerized pharmaceutical information system that meets the             |  |  |
| 1142 |    | ,   | standards of performance required by the regulations of the Drug          |  |  |
| 1143 |    |   | Enforcement Administration (21 CFR 1306; 2014) and shall                  |  |  |
| 1144 |    |   | include the capability to:  |  |  |
| 1145 |    |   | 1 3   |  |  |
| 1146 |    |   | i) Retrieve the original medication order information for                 |  |  |
| 1147 |    |   | those medication orders that are currently authorized;                    |  |  |
| 1148 |    |   | ,   |  |  |
| 1149 |    |   | ii) Retrieve the current history of medication orders that shall,         |  |  |
| 1150 |    |   | at a minimum, include the name of drug, the date of filling               |  |  |
| 1151 |    |   | the quantity dispensed, the name and identification code of               |  |  |
| 1152 |    |   | manufacturer in the case of a generically written                         |  |  |
| 1153 |    |   | prescription or a generic interchange, for each filling, and              |  |  |
| 1154 |    |   | the total number of refills when read in conjunction with                 |  |  |
| -    |    |   |   |  |  |

| 1155<br>1156 |    |                        |                       |           | any off-line hard copy of the history of medication orders dispensed to date; and  |  |  |
|--------------|----|------------------------|-----------------------|-----------|--|--|--|
| 1157         |    |                        |                       | •••       |  |  |  |
| 1158         |    |                        |                       | iii)      | Supply documentation of the correctness of filling   |  |  |
| 1159         |    |                        |                       |           | information entered into a system must be provided by the  |  |  |
| 1160         |    |                        |                       |           | pharmacist using the system by way of a hard copy printout   |  |  |
| 1161         |    |                        |                       |           | of each day's filling data that has been verified, dated and   |  |  |
| 1162         |    |                        |                       |           | signed by the dispensing pharmacist; or  |  |  |
| 1163         |    |                        | <b>D</b> )            |           | 1 1 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1   |  |  |
| 1164         |    |                        | B)                    |           | logbook log book, or separate file, in which each individual   |  |  |
| 1165         |    |                        |                       | _         | acist involved in dispensing shall sign a statement each day   |  |  |
| 1166         |    |                        |                       |           | ng to the fact that the refill information entered into the  |  |  |
| 1167         |    |                        |                       | -         | ater that day has been reviewed by him/her and is correct as   |  |  |
| 1168         |    |                        |                       |           | The book or file must be maintained at the pharmacy  |  |  |
| 1169         |    |                        |                       | -         | ying the system for a period of 5 years after the date of  |  |  |
| 1170         |    |                        |                       | disper    | sing the appropriately authorized refill.  |  |  |
| 1171         | ۵) | Too 4le e              | 41                    | م ما ما   | townland town constantition of one of the second se |  |  |
| 1172         | c) |                        |                       |           | termlong term care facility changes pharmacy provider  |  |  |
| 1173         |    |                        |                       | -         | rovider must obtain the orders from the long-termlong term   |  |  |
| 1174<br>1175 |    |                        | •                     | ina vern  | by the authenticity and accuracy of the orders with the  |  |  |
| 1175<br>1176 |    | presc                  | riber.                |           |  |  |  |
| 1170<br>1177 | d) | Stoff                  | ing of th             | a Dharm   | nacy. When the pharmacy is closed, the public and any  |  |  |
| 1177         | u) |                        | _                     |           | ered under the Act are to be prohibited access to the filling  |  |  |
| 1178<br>1179 |    | -                      | dispensin             | _         | ered under the Act are to be promotica access to the mining  |  |  |
| 1180         |    | and C                  | перспеш               | ig area.  |  |  |  |
| 1181         | e) | Lahe                   | Labeling Requirements |           |  |  |  |
| 1182         | C) | Date in a requirements |                       |           |  |  |  |
| 1183         |    | 1)                     | Media                 | rations f | For Future Use   |  |  |
| 1184         |    | 1)                     | Modic                 |           | of Future Cisc   |  |  |
| 1185         |    |                        | A)                    | Parent    | teral solutions to which a drug or diluent has been added or   |  |  |
| 1186         |    |                        | 11)                   |           | re not in their original manufacturer's packaging shall contain  |  |  |
| 1187         |    |                        |                       |           | llowing information on the outer label:  |  |  |
| 1188         |    |                        |                       | the ro    | nowing information on the other facer.   |  |  |
| 1189         |    |                        |                       | i)        | Name, concentration and volume of the base parenteral  |  |  |
| 1190         |    |                        |                       | 1)        | solution;  |  |  |
| 1191         |    |                        |                       |           | solution,  |  |  |
| 1192         |    |                        |                       | ii)       | Name and strength of drugs added;  |  |  |
| 1193         |    |                        |                       | 11)       | The stronger of drags added,   |  |  |
| 1194         |    |                        |                       | iii)      | Beyond use date and date of the admixture. Beyond use  |  |  |
| 1195         |    |                        |                       | 111)      | date, unless otherwise specified in the individual   |  |  |
| 1196         |    |                        |                       |           | <u>-</u>   |  |  |
|              |    |                        |                       |           | compendia monograph shall be not later than the beyond   |  |  |

| 1197<br>1198 |    |       |               | use date on the manufacturer's container or one year from<br>the date the drug is repackaged, whichever is earlier; and |
|--------------|----|-------|---------------|---|
| 1199         |    |       |               | the date the drug is repuekaged, whichever is earlier, and  |
| 1200         |    |       | iv)           | Reference code to identify source and lot number of drugs   |
| 1201         |    |       | 11)           | added.  |
| 1202         |    |       |               | udded.  |
| 1203         |    | B)    | Non-r         | parenterals repackaged for future use shall be identified with  |
| 1204         |    | D)    | -             | llowing information:  |
| 1205         |    |       | the ro        | nowing information.   |
| 1206         |    |       | i)            | Brand and/or generic name;  |
| 1207         |    |       | 1)            | Brand and/or generic name,  |
| 1208         |    |       | ii)           | Strength (if applicable);   |
| 1209         |    |       | 11)           | Suchgui (ii applicatio),  |
| 1210         |    |       | iii)          | Beyond use date. Unless otherwise specified in the  |
| 1210         |    |       | 111)          | individual monograph, the beyond use date shall be not  |
| 1211         |    |       |               | later than the beyond use date on the manufacturer's  |
| 1212         |    |       |               | container or one year from the date the drug is repackaged.   |
| 1213         |    |       |               | whichever is earlier; and   |
| 1214         |    |       |               | whichever is carrier, and   |
| 1216         |    |       | iv)           | Reference code to identify source and lot number.   |
| 1217         |    |       | 10)           | Reference code to identify source and for number.   |
| 1217         | 2) | Media | cations       | Prepared for Immediate Use  |
| 1219         | 2) | Wican | cations       | repared for immediate ose   |
| 1220         |    | A)    | All m         | edications prepared by the pharmacy for immediate   |
| 1221         |    | Α)    |               | using to a specific resident or patient in the facility shall be  |
| 1222         |    |       |               | nsed in a container identified with:  |
| 1223         |    |       | disper        | ised in a container identified with.  |
| 1224         |    |       | i)            | Name of the resident;   |
| 1225         |    |       | 1)            | value of the resident,  |
| 1226         |    |       | ii)           | Resident's room and bed number;   |
| 1227         |    |       | 11)           | Resident's room and oed number,   |
| 1228         |    |       | iii)          | Dispensing date;  |
| 1229         |    |       | 111)          | Dispensing date,  |
| 1230         |    |       | iv)           | Name, strength and dosage form of drug, or description of   |
| 1231         |    |       | 11)           | the medical device ordered;   |
| 1232         |    |       |               | the medical device ordered,   |
| 1232         |    |       | v)            | Quantity dispensed;   |
| 1234         |    |       | <b>v</b> )    | Quality dispensed,  |
| 1234         |    |       | vi)           | Directions for use;   |
| 1236         |    |       | v1 <i>)</i>   | Directions for use,   |
| 1230<br>1237 |    |       | vii)          | Prescriber's name; and  |
| 1238         |    |       | v 11 <i>)</i> | reserred s name, and  |
|              |    |       |               |   |

| 1220         |            |               | :::      | David was data if less than 60 days from data of               |
|--------------|------------|---------------|----------|--|
| 1239<br>1240 |            |               | viii)    | Beyond use date if less than 60 days from date of              |
| 1240         |            |               |          | dispensing.  |
| 1241         |            | B)            | Dhorm    | acies dispensing medications to a specific resident or patient |
| 1242         |            | В)            |          | facility via unit dose shall label each order with the         |
| 1243         |            |               |          | ing information:   |
| 1245         |            |               | IOHOW    | ing information.   |
| 1245         |            |               | i)       | Name of the resident;  |
| 1247         |            |               | 1)       | Name of the resident,  |
| 1248         |            |               | ii)      | Resident's room and bed number;                                |
| 1249         |            |               | 11)      | resident's room and bed namber,                                |
| 1250         |            |               | iii)     | Date of order;   |
| 1251         |            |               | 111)     | Date of order,   |
| 1252         |            |               | iv)      | Name, strength and dosage form of drug, or description of      |
| 1253         |            |               | 11)      | the medical device ordered;                                    |
| 1254         |            |               |          | the medical device of defed,                                   |
| 1255         |            |               | v)       | Directions for use; and  |
| 1256         |            |               | • /      |  |
| 1257         |            |               | vi)      | Prescriber's name.   |
| 1258         |            |               |          |  |
| 1259         | f)         | Pharmacies th | at com   | bound and dispense sterile products shall comply with          |
| 1260         | ,          | Section 1330. | _        | 1 1 1 7  |
| 1261         |            |               |          |  |
| 1262         | g)         | Medication Di | ispensir | ng in the Absence of a Pharmacist. The availability of         |
| 1263         | <i>U</i> , |               | -        | s for immediate therapeutic use during those hours when the    |
| 1264         |            |               |          | y is not open shall be met in the following manner:            |
| 1265         |            | •             | •        | , ,  |
| 1266         |            | 1) An afte    | er-hour  | cabinet, which is a locked cabinet or other enclosure located  |
| 1267         |            | outside       | e of the | pharmacy area containing a minimal supply of the most          |
| 1268         |            | freque        | ntly req | uired medication, may be utilized provided that only           |
| 1269         |            | person        | nel spec | cifically authorized by the institution in which the pharmacy  |
| 1270         |            | is loca       | ted may  | obtain access and it is sufficiently secure to deny access to  |
| 1271         |            | unauth        | orized j | persons. After-hour cabinets shall only be used in the         |
| 1272         |            | absenc        | e of a p | harmacist. When medication is removed from the cabinet or      |
| 1273         |            | enclos        | ure, wri | tten physician's orders authorizing the removal of the         |
| 1274         |            | medica        | ation sh | all be placed in the cabinet or enclosure. A log shall be      |
| 1275         |            | mainta        | ined wi  | thin the cabinet or enclosure and authorized personnel         |
| 1276         |            | remov         | ing med  | lication shall indicate on the log the signature of the        |
| 1277         |            | author        | ized pei | sonnel removing the medication, the name of the medication     |
| 1278         |            |               |          | strength (if applicable), the quantity removed and the time of |
| 1279         |            |               |          | utomated dispensing and storage system may be used as an       |
| 1280         |            |               |          | oinet. This use shall be in compliance with Section            |
| 1281         |            | 1330.6        | 580.     |  |

1282 1283 2) Emergency kits containing those drugs that may be required to meet the immediate therapeutic needs of the patient, and that are not available from 1284 1285 any other source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other source, may be 1286 1287 utilized. Emergency kits shall be supplied and maintained under the 1288 supervision of a pharmacist. Drugs shall be removed from emergency kits 1289 only by authorized pharmacy personnel or persons authorized to administer medication pursuant to a valid physician's order of a physician 1290 licensed to practice medicine in all of its branches in Illinois. Emergency 1291 1292 kits shall be sealed in some manner that will indicate when the kit has 1293 been opened. A label shall be affixed to the outside of the emergency kit 1294 indicating the beyond use date of the emergency kit. The beyond use date 1295 of the emergency kit shall be the earliest beyond use date of any drug 1296 contained in the kit. After an emergency kit has been used or upon discovery that the seal has been broken or upon the occurrence of the 1297 beyond use date, the kit shall be secured and returned to the pharmacy to 1298 1299 be checked and/or restocked by the last authorized user. If the pharmacy is closed at that time, the kit shall be returned when it opens. An automated 1300 1301 dispensing and storage system may be used as an emergency kit. This use 1302 shall be in compliance with Section 1330.680. 1303 1304 3) Whenever any drug is not available from night cabinets or emergency kits, 1305 and the drug is required to treat the immediate needs of a patient, the drug may be obtained from the pharmacy in sufficient quantity to meet the 1306 immediate need by an authorized nurse. When medication is removed 1307 1308 from the pharmacy by an authorized nurse, a copy of the physician's order 1309 authorizing the removal of the medication shall be conspicuously placed in 1310 the pharmacy with the container from which the drug was removed so that 1311 it will be found by a pharmacist and checked promptly. A form shall be 1312 available in the pharmacy upon which shall be recorded the signature of the authorized nurse who removed the medication, the name, strength (if 1313 applicable) and quantity of medication removed. 1314 1315 (Source: Amended at 47 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_) 1316 1317 1318 Section 1330.530 Onsite Institutional Pharmacy Services 1319 1320 a) Onsite Pharmacies Pharmacies located in facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, or the University of Illinois Hospital 1321 1322 Act, or that are operated by the Department of Human Services or the Department

of Corrections, and that provide pharmacy services to residents, patients.

1323

| 1324 |    | employees, prescribers and students of these facilities, shall, in addition to other |                     |   |  |  |
|------|----|--|---------------------|---|--|--|
| 1325 |    | require  | <del>ements (</del> | of the Act and this Part, comply with this Section.   |  |  |
| 1326 |    |  |                     |   |  |  |
| 1327 |    | <u>1)</u>  | A phar              | macy located in facilities licensed under the Nursing Home Care   |  |  |
| 1328 |    |  | Act, th             | e Hospital Licensing Act, or the University of Illinois Hospital Act,   |  |  |
| 1329 |    |  | or that             | are operated by the Department of Human Services or the   |  |  |
| 1330 |    |  | Depart              | ment of Corrections, and that provide pharmacy services to  |  |  |
| 1331 |    |  | resider             | nts, patients, employees, prescribers and students of these facilities,   |  |  |
| 1332 |    |  |                     | n addition to other requirements of the Act and this Part, comply   |  |  |
| 1333 |    |  |                     | nis Section.  |  |  |
| 1334 |    |  |                     |   |  |  |
| 1335 |    | <u>2)</u>  | A phar              | macy that is not located in the facilities it serves and the facilities it  |  |  |
| 1336 |    |  | _                   | are licensed under the Illinois Department of Human Services,   |  |  |
| 1337 |    |  | •                   | on of Substance Use Prevention and Recovery, for the prevention,  |  |  |
| 1338 |    |  |                     | ention, treatment, and recovery support of substance use disorders or   |  |  |
| 1339 |    |  |                     | treatment of mental health.   |  |  |
| 1340 |    |  |                     |   |  |  |
| 1341 | b) | Record   | lkeenin             | g Requirements  |  |  |
| 1342 | -/ |  | I                   | 6 1·····  |  |  |
| 1343 |    | 1)   | Every               | prescription or medication order filled or refilled shall contain the   |  |  |
| 1344 |    | -/   | •                   | initials or other unique identifier of the pharmacist (and pharmacy   |  |  |
| 1345 |    |  |                     | cian if one is used) who fills or refills the prescription or medication  |  |  |
| 1346 |    |  |                     | or the name, initials or other unique identifier may be recorded on   |  |  |
| 1347 |    |  |                     | r appropriate, uniformly maintained and readily retrievable record  |  |  |
| 1348 |    |  |                     | dicates, at least, the following information:   |  |  |
| 1349 |    |  | 011000 1111         | and and a second and some many and a second |  |  |
| 1350 |    |  | A)                  | The name and dosage form of the drug;   |  |  |
| 1351 |    |  | /                   | The name and cooling form of the drug,  |  |  |
| 1352 |    |  | B)                  | The date of filling or refilling; and   |  |  |
| 1353 |    |  | 2)                  | The date of fining of ferming, and  |  |  |
| 1354 |    |  | C)                  | The quantity dispensed.   |  |  |
| 1355 |    |  | <i>C)</i>           | The quality dispensed.  |  |  |
| 1356 |    | 2)   | No pre              | escription may be dispensed for a period in excess of 15 monthsone  |  |  |
| 1357 |    | _/   | -                   | om the date of the original issuance of the prescription by the   |  |  |
| 1358 |    |  | prescri             |   |  |  |
| 1359 |    |  | preseri             |   |  |  |
| 1360 |    | 3)   | The ph              | narmacist-in-charge shall maintain or have access to the following  |  |  |
| 1361 |    | -/   | _                   | s for at least 5 years or as otherwise required by law:   |  |  |
| 1362 |    |  | 10010               | 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 -   |  |  |
| 1363 |    |  | A)                  | Records of medication orders and medication administration to   |  |  |
| 1364 |    |  | 11)                 | patients;   |  |  |
| 1365 |    |  |                     | pations,  |  |  |
| 1366 |    |  | B)                  | Procurement records for controlled substances;  |  |  |
| 1500 |    |  | D)                  | 1 Total Children Total Controlled Substances,   |  |  |

| 1367 |    |      |          |           |   |
|------|----|------|----------|-----------|---|
| 1368 |    |      | C)       | Recor     | ds of packaging, bulk compounding or manufacturing; and           |
| 1369 |    |      |          |           |   |
| 1370 |    |      | D)       | Recor     | ds of actions taken pursuant to drug recalls.                     |
| 1371 |    |      |          |           |   |
| 1372 | c) | Labe | ling Rec | quiremei  | nts   |
| 1373 |    |      |          |           |   |
| 1374 |    | 1)   | All m    | edicatio  | n repackaged by the pharmacy for future use inside the            |
| 1375 |    |      | institu  | ution or  | facility and not intended for immediate dispensing to a           |
| 1376 |    |      | specif   | fic patie | nt shall be identified as follows:                                |
| 1377 |    |      |          |           |   |
| 1378 |    |      | A)       | Single    | dose or multi-dose drugs, except sterile solutions to which a     |
| 1379 |    |      |          | drug l    | has been added, shall be labeled with:                            |
| 1380 |    |      |          |           |   |
| 1381 |    |      |          | i)        | Brand and/or generic name;  |
| 1382 |    |      |          |           | -   |
| 1383 |    |      |          | ii)       | Strength (if applicable);   |
| 1384 |    |      |          |           |   |
| 1385 |    |      |          | iii)      | Beyond use date; and  |
| 1386 |    |      |          |           | •   |
| 1387 |    |      |          | iv)       | Reference code to identify source and lot number.                 |
| 1388 |    |      |          |           | ·   |
| 1389 |    |      | B)       | Sterile   | e solutions to which drugs have been added shall contain on       |
| 1390 |    |      |          |           | ter label:  |
| 1391 |    |      |          |           |   |
| 1392 |    |      |          | i)        | Name, concentration and volume of the base sterile                |
| 1393 |    |      |          | ,         | solution;   |
| 1394 |    |      |          |           | ,   |
| 1395 |    |      |          | ii)       | Name and strength of drugs added;                                 |
| 1396 |    |      |          | ,         |   |
| 1397 |    |      |          | iii)      | Beyond use date and time of the admixture; and                    |
| 1398 |    |      |          | ,         | .,  |
| 1399 |    |      |          | iv)       | Reference code to identify source and lot number of drugs         |
| 1400 |    |      |          | ,         | added.  |
| 1401 |    |      |          |           |   |
| 1402 |    | 2)   | All m    | edicatio  | n prepared by the pharmacy for immediate dispensing to a          |
| 1403 |    | -/   |          |           | nt or resident in the institution or facility shall be identified |
| 1404 |    |      | as fol   | -         | ., ., ., ., ., ., ., ., ., ., ., ., ., .                          |
| 1405 |    |      |          |           |   |
| 1406 |    |      | A)       | Single    | e dose or multi-dose drugs, except parenteral solutions to        |
| 1407 |    |      | /        | _         | a drug has been added, shall be identified with:                  |
| 1408 |    |      |          |           |   |
| 1409 |    |      |          | i)        | Brand and/or generic name; and                                    |
|      |    |      |          | -/        | ,   |

| 1410         |     |            | ••        |   |
|--------------|-----|------------|-----------|---|
| 1411         |     |            | ii)       | Strength (if applicable).   |
| 1412         |     | D)         | C411 -    |   |
| 1413         |     | B)         |           | solutions to which drugs have been added shall be identified  |
| 1414         |     |            | with:     |   |
| 1415         |     |            | :\        | Name and antiquities and values of the base sterile   |
| 1416         |     |            | i)        | Name, concentration and volume of the base sterile  |
| 1417         |     |            |           | solution;   |
| 1418         |     |            | ::\       | Nome and strength of days and dady and  |
| 1419<br>1420 |     |            | ii)       | Name and strength of drugs added; and   |
| 1420         |     |            | :::)      | Davond was data and time of the admirture   |
| 1421<br>1422 |     |            | iii)      | Beyond use date and time of the admixture.  |
| 1422<br>1423 |     | C)         | A 11 ma   | diagtion dispensed to a specific patient in the institution   |
| 1423<br>1424 |     | <b>C</b> ) |           | edication dispensed to a specific patient in the institution e dispensed in a container identified with the name of the |
| 1424<br>1425 |     |            |           | and the patient's location. Those institutions or facilities  |
| 1425<br>1426 |     |            | -         | ng a unit-dose and medication cart system may identify the  |
| 1427         |     |            |           | of the patient and the patient's location on the outside of the   |
| 1428         |     |            |           | the medication cart, when those carts are filled by the   |
| 1429         |     |            | pharma    | · · · · · · · · · · · · · · · · · · ·   |
| 1430         |     |            | pnam      | ucy.  |
| 1431         | 3)  | Labels     | on all r  | medications dispensed by the pharmacy for immediate   |
| 1432         | - / |            |           | a patient being discharged, emergency room patient and/or   |
| 1433         |     | -          | _         | ll contain the following:   |
| 1434         |     | p,         | ,         |   |
| 1435         |     | A)         | The na    | me and dosage form of the drug;   |
| 1436         |     | ,          |           | 5   |
| 1437         |     | B)         | The da    | te filled;  |
| 1438         |     | ŕ          |           |   |
| 1439         |     | C)         | The qu    | antity dispensed; and   |
| 1440         |     |            | _         |   |
| 1441         |     | D)         | Directi   | ions for use.   |
| 1442         |     |            |           |   |
| 1443         | 4)  | Investi    | gationa   | l new drugs, authorized by the U.S. Food and Drug   |
| 1444         |     |            |           | n, shall be dispensed pursuant to a valid prescription order of   |
| 1445         |     | the pri    | ncipal p  | hysician-investigator or his authorized clinician. All  |
| 1446         |     | investi    | gationa   | l drugs shall be stored in and dispensed from the pharmacy  |
| 1447         |     | and sha    | all be id | lentified with the following information:   |
| 1448         |     |            |           |   |
| 1449         |     | A)         | Name      | of drug and strength (if applicable);   |
| 1450         |     |            |           |   |
| 1451         |     | B)         | Beyon     | d use date;   |
| 1452         |     |            |           |   |

| 1453         |    |         | C)       | Reference code to identify source and lot number;  |
|--------------|----|---------|----------|--|
| 1454         |    |         |          |  |
| 1455         |    |         | D)       | A label indicating "For Investigational Use Only"; and   |
| 1456         |    |         |          |  |
| 1457         |    |         | E)       | Name and location of the patient. Those institutions or facilities   |
| 1458         |    |         |          | utilizing a unit-dose and medication cart system may identify the  |
| 1459         |    |         |          | name of the patient and the patient's location on the outside of the   |
| 1460         |    |         |          | bin of the medication cart, when those carts are filled by the   |
| 1461         |    |         |          | pharmacy.  |
| 1462         |    |         |          |  |
| 1463         |    | 5)      | A phar   | macist providing a copy of a prescription to an ultimate consumer  |
| 1464         |    |         | for the  | purpose of transfer or any other purpose shall cancel the face of the  |
| 1465         |    |         |          | al prescription and record the date the copy is issued, to whom  |
| 1466         |    |         | _        | and the pharmacist's signature on the face of the original   |
| 1467         |    |         |          | ption. Copies of prescriptions shall be marked "For Information  |
| 1468         |    |         |          | ses Only" and require prescriber authorization to fill.  |
| 1469         |    |         | 1        | 7 1 1  |
| 1470         | d) | Staffin | g of the | Pharmacy   |
| 1471         | /  |         | 6        | <b>,</b>   |
| 1472         |    | 1)      | The re   | sponsibilities of the pharmacist-in-charge shall include:  |
| 1473         |    | -/      | 1110 10  | opensional and priming in energy simil merous.   |
| 1474         |    |         | A)       | Supervision of all the activities of all employees as they relate to   |
| 1475         |    |         | /        | the practice of pharmacy;  |
| 1476         |    |         |          | the practice of pharmacy,  |
| 1477         |    |         | B)       | Establishment and supervision of the method and manner for   |
| 1478         |    |         | 2)       | storage, dispensing and safekeeping of pharmaceuticals in all areas  |
| 1479         |    |         |          | of the institution or facility, including maintenance of security  |
| 1480         |    |         |          | provisions to be used when the pharmacy is closed. The following   |
| 1481         |    |         |          | security provisions shall be utilized:   |
| 1482         |    |         |          | security provisions shall be utilized.   |
| 1483         |    |         |          | i) The pharmacy shall be staffed at all times by a registered  |
| 1484         |    |         |          | pharmacist during open hours; and  |
| 1485         |    |         |          | pharmacist during open nours, and  |
| 1486         |    |         |          | ii) Only registrants and licensees shall have access to the  |
| 1480<br>1487 |    |         |          | pharmacy, except as provided in Section 1330.530(e)(1);  |
| 1488         |    |         |          | pharmacy, except as provided in Section 1330.330(e)(1),  |
| 1489         |    |         | C)       | Establishment and supervision of the recordkeeping system for the  |
| 1409         |    |         | C)       | <u> </u>   |
| 1490<br>1491 |    |         |          | purchase, sale, delivery, possession, storage and safekeeping of   |
|              |    |         |          | drugs;   |
| 1492         |    |         | D)       | The development and implementation of a precedure to be utilized.  |
| 1493<br>1404 |    |         | D)       | The development and implementation of a procedure to be utilized in the event of a drug recall that can be readily activated to assure |
| 1494         |    |         |          | in the event of a drug recall that can be readily activated to assure  |
|              |    |         |          |  |

| 1495 |    |        | that all drugs included on the recall are returned to the pharmacy      |
|------|----|--------|---|
| 1496 |    |        | for proper disposition;   |
| 1497 |    |        |   |
| 1498 |    | E)     | Establishment of specifications for the procurement of all drugs        |
| 1499 |    |        | that will be dispensed by the pharmacy; and                             |
| 1500 |    |        |   |
| 1501 |    | F)     | Establishment and supervision of a method of documenting an oral        |
| 1502 |    |        | prescription from a licensed physician to a pharmacist and for          |
| 1503 |    |        | transmission of that information to the appropriate members of the      |
| 1504 |    |        | nursing staff of the institution or facility.                           |
| 1505 |    |        |   |
| 1506 | 2) | The o  | perations of the pharmacy and the maintenance of security               |
| 1507 |    | provis | sions are the responsibility of the pharmacist-in-charge whether the    |
| 1508 |    | -      | r is a sole proprietor, partnership, association, corporation or any    |
| 1509 |    |        | entity.   |
| 1510 |    |        | ·   |
| 1511 | 3) | Withi  | n 30 days after the change of a pharmacist-in-charge, the Division      |
| 1512 | ,  |        | be notified in writing by the departing pharmacist-in-charge.           |
| 1513 |    |        |   |
| 1514 | 4) | The d  | eparting pharmacist-in-charge shall, on the effective date of the       |
| 1515 | ,  |        | e, inventory the following controlled substances:                       |
| 1516 |    |        | •   |
| 1517 |    | A)     | All Schedule II drugs, as defined in the Illinois Controlled            |
| 1518 |    | ,      | Substances Act, by actual physical count; and                           |
| 1519 |    |        | , , ,   |
| 1520 |    | B)     | All other scheduled drugs, as defined in the Illinois Controlled        |
| 1521 |    | ,      | Substances Act, by estimated count.                                     |
| 1522 |    |        | , ,   |
| 1523 | 5) | The in | nventory shall constitute, for the purpose of this Section, the closing |
| 1524 | ,  |        | tory of the departing pharmacist-in-charge and the initial inventory    |
| 1525 |    |        | incoming pharmacist-in-charge. This inventory record shall be           |
| 1526 |    |        | rved in the pharmacy for a period of 5 years. An affidavit attesting to |
| 1527 |    | -      | ompletion and preservation of the inventory record bearing the date     |
| 1528 |    |        | inventory and the signatures of the departing and incoming              |
| 1529 |    |        | nacist-in-charge shall be submitted to the Division, at its principal   |
| 1530 |    | -      | e, within 30 days after the change in the pharmacist-in-charge.         |
| 1531 |    | 011100 | , within 50 days area the change in the pharmaeist in charge.           |
| 1532 | 6) | Failur | re on the part of a registrant to provide the affidavit required in     |
| 1533 | ٥) |        | ctions (d)(4) and (5) shall be grounds for denying an application or    |
| 1534 |    |        | val application for a pharmacy license or for disciplinary action       |
| 1535 |    |        | st a registrant. Denial shall be based on the recommendation of the     |
| 1536 |    | Board  | _   |
| 1537 |    | 20010  |   |
|      |    |        |   |

| 1538<br>1539<br>1540<br>1541<br>1542<br>1543<br>1544 |    | 7)       | invente<br>charge<br>pharm<br>pharm<br>respon | event the departing pharmacist-in-charge refuses to complete the ory as provided for in subsection (d)(4), or that pharmacist-in- is incapacitated or deceased, the initial inventory for the incoming acist-in-charge shall be the inventory as completed by the incoming acist-in-charge. The incoming pharmacist-in-charge will not be asible for any discrepancy that may exist in the inventory prior to his initial inventory. |
|--|----|----------|---|--|
| 1545   |    | 0)       | ***   |  |
| 1546   |    | 8)       |   | the accuracy, relevance or completeness of any submitted   |
| 1547<br>1548   |    |          |   | nentation is reasonably questioned by the Division because of lack of  |
| 1549   |    |          |   | nation, discrepancies or conflicts in information given, or a need for   |
| 1550   |    |          | Clarific                                      | cation, the registrant will be required to:  |
| 1551   |    |          | A)  | Provide information as may be necessary; and/or  |
| 1552   |    |          | A)  | 1 Tovide information as may be necessary, and/or   |
| 1553   |    |          | B)  | Appear for an interview before the Board to explain the relevance  |
| 1554   |    |          | D)  | or sufficiency, clarify information given or clear up any  |
| 1555   |    |          |   | discrepancies or conflicts in information.   |
| 1556   |    |          |   | discrepancies of commets in information  |
| 1557   |    | 9)       | Pharm   | acists and pharmacies are prohibited from accepting from patients  |
| 1558   |    | - /      |   | r agents for reuse, reissue or resale dispensed medications,   |
| 1559   |    |          |   | cals, poisons or medical devices, except for:  |
| 1560   |    |          |   | , 1  |
| 1561   |    |          | A)  | Medical devices that can be properly sanitized prior to reuse, resale  |
| 1562   |    |          | ŕ   | or re-rent; and  |
| 1563   |    |          |   |  |
| 1564   |    |          | B)  | Medications that are dispensed and stored under conditions defined   |
| 1565   |    |          |   | and supervised by the pharmacist and are unopened in sealed,   |
| 1566   |    |          |   | intact and unaltered containers that meet the standards for light,   |
| 1567   |    |          |   | moisture and air permeation as defined by a current United States  |
| 1568   |    |          |   | Pharmacopoeia/National Formulary published by the United States  |
| 1569   |    |          |   | Pharmacopoeial Convention, Inc.  |
| 1570   |    |          |   |  |
| 1571   | e) | Medica   | ation D                                       | ispensing in the Absence of a Pharmacist. The availability of  |
| 1572   |    | necess   | ary med                                       | dications for immediate therapeutic use during those hours when the  |
| 1573   |    | institut | ional p                                       | harmacy is not open shall be met in the following manner:  |
| 1574   |    |          |   |  |
| 1575   |    | 1)       |   | er-hour cabinet, which is a locked cabinet or other enclosure located  |
| 1576   |    |          |   | e of the pharmacy area containing a minimal supply of the most   |
| 1577   |    |          | -   | ntly required medication, may be utilized provided that only   |
| 1578   |    |          |   | inel specifically authorized by the institution in which the pharmacy  |
| 1579   |    |          |   | ted may obtain access and it is sufficiently secure to deny access to  |
| 1580   |    |          | unauth  | norized persons. After-hour cabinets shall only be used in the   |

1611

1619 1620 1621

1617

1618

1622 1623 absence of a pharmacist. When medication is removed from the cabinet or enclosure, written physician's orders authorizing the removal of the medication shall be placed in the cabinet or enclosure. A log shall be maintained within the cabinet or enclosure and authorized personnel removing medication shall indicate on the log the signature of the authorized personnel removing the medication, name of the medication removed, the strength (if applicable), the quantity removed and the time of removal. An automated dispensing and storage system may be used as an after hours cabinet. This use shall be in compliance with Section 1330.680.

- 2) Emergency kits containing those drugs that may be required to meet the immediate therapeutic needs of the patient, and that are not available from any other source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other source, may be utilized. Emergency kits shall be supplied and maintained under the supervision of a pharmacist. Drugs shall be removed from emergency kits only by authorized pharmacy personnel, persons authorized to administer medication pursuant to a valid physician's order of a physician licensed to practice medicine in all of its branches in Illinois. Emergency kits shall be sealed in some manner that will indicate when the kit has been opened. A label shall be affixed to the outside of the emergency kit indicating the beyond use date of the emergency kit. The beyond use date of the emergency kit shall be the earliest beyond use date of any drug contained in the kit. After an emergency kit has been used or upon discovery that the seal has been broken or upon the occurrence of the beyond use date, the kit shall be secured and returned to the pharmacy to be checked and/or restocked by the last authorized user. If the pharmacy is closed at such time, the kit shall be returned when it opens. An automated dispensing and storage system may be used as an emergency kit. This use shall be in compliance with Section 1330.680.
- 3) Whenever any drug is not available from night cabinets or emergency kits, and the drug is required to treat the immediate needs of a patient, the drug may be obtained from the pharmacy in sufficient quantity to meet the immediate need by an authorized nurse. When medication is removed from the pharmacy by an authorized nurse, a copy of the physician's order authorizing the removal of the medication shall be conspicuously placed in the pharmacy with the container from which the drug was removed so that it will be found by a pharmacist and checked promptly. A form shall be available in the pharmacy upon which shall be recorded the signature of the authorized nurse who removed the medication, the name, strength (if applicable) and quantity of medication removed.

| 1624 |              |   |
|------|--------------|---|
| 1625 |              | 4) Drugs may be dispensed from the emergency room only by a practitioner            |
| 1626 |              | licensed to prescribe and dispense, and only to patients treated in the             |
| 1627 |              | institution. This shall occur only during hours in which outpatient                 |
| 1628 |              | institutional pharmacy services are not available. The quantity dispensed           |
| 1629 |              | should be limited to no more than a 72 hour supply, except for                      |
| 1630 |              | antimicrobial drugs and unit of use packages (e.g., inhalers, ophthalmic,           |
| 1631 |              | otics, etc.), to meet the immediate needs of the patient until pharmacy             |
| 1632 |              | services are available. Drugs dispensed in this manner must meet all                |
| 1633 |              | labeling requirements pertaining to community pharmacies as specified in            |
| 1634 |              | Section 1330.500. There shall be written policies and procedures,                   |
| 1635 |              | approved by the medical staff, regarding the dispensing of drugs from the           |
| 1636 |              | emergency room.   |
| 1637 |              |   |
| 1638 | f)           | Pharmacies that compound and dispense sterile products shall comply with            |
| 1639 |              | Section 1330.640.   |
| 1640 |              |   |
| 1641 | g)           | Pharmacies that utilize automated dispensing and storage systems shall comply       |
| 1642 |              | with Section 1330.680.  |
| 1643 |              |   |
| 1644 | (Sour        | ce: Amended at 47 Ill. Reg, effective)  |
| 1645 |              |   |
| 1646 |              | SUBPART F: PHARMACY STANDARDS   |
| 1647 |              |   |
| 1648 | Section 1330 | .610 Pharmacy Structural/Equipment Standards  |
| 1649 |              |   |
| 1650 | All pharmaci | es must comply with the following provisions:                                       |
| 1651 |              |   |
| 1652 | a)           | Notification shall be submitted to the Division that an existing pharmacy will be   |
| 1653 |              | remodeled.  |
| 1654 | • `          |   |
| 1655 | b)           | Other than on-site institutional pharmacies, all dispensing, and drug storage areas |
| 1656 |              | of the pharmacy must be contiguous and have a connecting door for access            |
| 1657 |              | between the pharmacy and drug storage area.   |
| 1658 |              |   |
| 1659 | c)           | The pharmacy area and all store rooms shall be well-lighted and properly            |
| 1660 |              | ventilated.   |
| 1661 | 1            |   |
| 1662 | d)           | Refrigerators shall be for the exclusive use of prescription drugs. No personal or  |
| 1663 |              | food items shall be stored in the refrigerator. Refrigeration shall be capable of   |
| 1664 |              | maintaining temperature within a range compatible with the proper storage of        |
| 1665 |              | drugs requiring refrigeration or freezing.  |
| 1666 |              |   |

| 1667  | e)           |           | armacy area shall not be used for storage of merchandise that interferes      |
|-------|--------------|-----------|---|
| 1668  |              | with the  | e practice of pharmacy.   |
| 1669  | £            | Ct.a.l.1  | a summent reference accordes sixtem in book on electronic data forms          |
| 1670  | f)           |           | e current reference sources, either in book or electronic data form           |
| 1671  |              |           | ble in the pharmacy or on-line), which shall include Facts and Comparisons    |
| 1672  |              |           | www.factsandcomparisons.com) or other suitable references determined by       |
| 1673  |              | the Div   | ision to be pertinent to the practice carried on in the licensed pharmacy.    |
| 1674  |              |           |   |
| 1675  | g)           | A telep   | hone shall be immediately accessible in the pharmacy area.                    |
| 1676  |              |           |   |
| 1677  | h)           | These r   | equirements are in addition to any other requirements found in this Part.     |
| 1678  |              |           |   |
| 1679  | i)           |           | nimum, the equipment and references listed in Section 1330.640 must be        |
| 1680  |              | maintai   | ned at all dispensing pharmacies.   |
| 1681  |              |           |   |
| 1682  | (Source      | ce: Ame   | nded at 47 Ill. Reg, effective)   |
| 1683  |              |           |   |
| 1684  |              |           | SUBPART G: PHARMACY OPERATIONS  |
| 1685  |              |           |   |
| 1686  | Section 1330 | .700 Pat  | tient Counseling  |
| 1687  |              |           |   |
| 1688  | a)           | Upon re   | eceipt of a new or refill prescription, a prospective drug regimen review or  |
| 1689  |              | drug ut   | ilization evaluation shall be performed. Prior to dispensing a prescription   |
| 1690  |              | to a nev  | w patient, a new <u>prescription</u> medication to an existing patient, or a  |
| 1691  |              | medica    | tion that has had a change in the dose, strength, route of administration or  |
| 1692  |              | direction | ons for use, the pharmacist, or a student pharmacist directed and supervised  |
| 1693  |              | by the p  | pharmacist, shall provide verbal counseling to the patient or patient's agent |
| 1694  |              | on perti  | inent medication information. An offer to counsel shall be made on all        |
| 1695  |              | other p   | rescriptions. Counseling shall include, but is not limited to:                |
| 1696  |              |           |   |
| 1697  |              | 1)        | Name and description of medication;   |
| 1698  |              |           |   |
| 1699  |              | 2)        | Dosage form and dosage;   |
| 1700  |              |           |   |
| 1701  |              | 3)        | Route of administration;  |
| 1702  |              |           |   |
| 1703  |              | 4)        | Duration of therapy;  |
| 1704  |              | ,         |   |
| 1705  |              | 5)        | Techniques for self-monitoring;   |
| 1706  |              | ,         |   |
| 1707  |              | 6)        | Proper storage;   |
| 1708  |              | -/        | · r · · · · · · · · · · · · · · · · · ·                                       |
| 1709  |              | 7)        | Refill information;   |
| -, 07 |              | ,,        | ,   |

| 1710 |    |        |  |
|------|----|--------|--|
| 1711 |    | 8)     | Actions to be taken in cases of missed doses;                                    |
| 1712 |    |        |  |
| 1713 |    | 9)     | Special directions and precautions for preparation, administration and use;      |
| 1714 |    |        |  |
| 1715 |    | 10)    | Common severe side effects, adverse effects, or interactions and                 |
| 1716 |    |        | therapeutic contraindications that may be encountered, including their           |
| 1717 |    |        | avoidance and the action required if they occur.                                 |
| 1718 |    |        |  |
| 1719 | b) | If, in | the pharmacist's professional judgment, oral counseling is not practicable for   |
| 1720 |    | the p  | atient or patient's agent, the pharmacist shall use alternative forms of patient |
| 1721 |    | infor  | mation. When used in place of oral counseling, alternative forms of patient      |
| 1722 |    | infor  | mation shall advise the patient or agent that the pharmacist may be contacted    |
| 1723 |    | for c  | onsultation in person at the pharmacy or by toll-free or collect telephone       |
| 1724 |    | servi  | ce.  |
| 1725 |    |        |  |
| 1726 | c) | Ever   | y licensed pharmacy directly serving patients at a physical location must        |
| 1727 |    | cons   | picuously post a sign provided by the Division containing a statement that the   |
| 1728 |    | patie  | nt has the right to counseling, the Division's consumer hotline number,          |
| 1729 |    | infor  | mation on how to file a complaint for failure to counsel, and any other          |
| 1730 |    |        | mation the Division deems appropriate. The sign must be printed in color ink     |
| 1731 |    | or di  | splayed electronically in color, measure at least 8½ x 11 inches in size, and    |
| 1732 |    | be po  | osted at either a cashier counter or waiting area clearly visible to patients.   |
| 1733 |    | Lice   | nsed pharmacies that do not maintain a physical location directly serving        |
| 1734 |    | patie  | ents must include a copy of the sign within any dispensed prescriptions. The     |
| 1735 |    | _      | will be available to download on the Division's website.                         |
| 1736 |    | C      |  |
| 1737 | d) | The 1  | pharmacist is responsible for maintaining patient profiles as defined in         |
| 1738 | ,  |        | on 3(s) of the Act. A reasonable effort shall be made to obtain information,     |
| 1739 |    | inclu  | ding, but not limited to, the following:   |
| 1740 |    |        |  |
| 1741 |    | 1)     | Name, date of birth (age), gender, address and telephone number;                 |
| 1742 |    |        |  |
| 1743 |    | 2)     | Individual history, when significant, including disease state, known             |
| 1744 |    |        | allergies, drug interactions, and a comprehensive list of medications and        |
| 1745 |    |        | relevant devices; and  |
| 1746 |    |        |  |
| 1747 |    | 3)     | Pharmacist's comments relevant to the individual's therapy.                      |
| 1748 |    |        |  |
| 1749 | e) | Patie  | ent identifiable information obtained by the pharmacist or the pharmacist's      |
| 1750 | ,  |        | gnee for the purpose of patient record maintenance, prospective drug review,     |
| 1751 |    | _      | utilization review and patient counseling shall be considered protected health   |
| 1752 |    | _      | rmation, as defined in Section 3(cc) of the Act. A pharmacist shall provide      |
|      |    |        | 1  |

| 1753    |               | counseling re | lated to protected health information in a discreet, supportive and    |
|---------|---------------|---------------|--|
| 1754    |               | informative r | nanner.  |
| 1755    |               |               |  |
| 1756    | f)            | A pharmacist  | at an on-site or off-site institutional pharmacy shall not be required |
| 1757    |               | to provide pa | tient counseling as required in this Section unless drugs are          |
| 1758    |               | dispensed by  | the pharmacy upon a patient's discharge from the institution.          |
| 1759    |               |               |  |
| 1760    | g)            | Nothing in th | is Section shall be construed as requiring a pharmacist to provide     |
| 1761    |               | counseling w  | hen a patient or patient's agent refuses such counseling. When a       |
| 1762    |               | _             | ient's agent refuses to accept patient counseling as provided in this  |
| 1763    |               | -             | refusal shall be documented.   |
| 1764    |               | ŕ             |  |
| 1765    | h)            | A pharmacist  | operating a remote pharmacy shall comply with the requirements of      |
| 1766    | ,             | -             | Counseling in those circumstances shall be done by both video and      |
| 1767    |               | audio means.  | · · · · · · · · · · · · · · · · · · ·                                  |
| 1768    |               |               |  |
| 1769    | (Source       | e: Amended a  | at 47 Ill. Reg, effective)   |
| 1770    | (             |               |  |
| 1771    | Section 1330. | 720 Transfer  | of Prescription  |
| 1772    |               |               |  |
| 1773    | a)            | A prescriptio | n may be transferred between pharmacies for the purpose of original    |
| 1774    | ,             |               | ispensing, provided that:  |
| 1775    |               |               | 8, F-1   |
| 1776    |               | 1) The tr     | ansfer of pharmacist transferring the prescription invalidates the     |
| 1777    |               |               | al prescription on file and records from to which pharmacy the         |
| 1778    |               | _             | ription was transferred, the date of issuance of the copy and the name |
| 1779    |               | -             | pharmacist, student pharmacist or pharmacy technician issuing the      |
| 1780    |               |               | erred prescription order; and  |
| 1781    |               |               | orrest presemption order, and  |
| 1782    |               | 2) The p      | harmacist, student pharmacist, or pharmacy technician receiving the    |
| 1783    |               | -             | erred prescription directly from the other pharmacypharmacist          |
| 1784    |               |               | ls the following:  |
| 1785    |               | 10001         | is the following.  |
| 1786    |               | A)            | The name, address and original prescription number of the              |
| 1787    |               | 11)           | pharmacy from which the prescription was transferred;                  |
| 1788    |               |               | pharmacy from which the prescription was transferred,                  |
| 1789    |               | B)            | All information constituting a prescription order, including the       |
| 1790    |               | D)            | following: name of the drug, original amount dispensed, date of        |
| 1791    |               |               | original issuance of the prescription, and number of valid refills     |
| 1792    |               |               | remaining; and   |
| 1793    |               |               | romaning, and  |
| 1794    |               | C)            | The pharmacist, student pharmacist, or pharmacy technician             |
| 1795    |               | Ο)            | receiving the transferred prescription informs the patient that the    |
| . 1 / / |               |               | 10001, mg die dansferrea preserration informs die patient that the     |

1796 original prescription has been cancelled at the pharmacy from 1797 which it has been transferred. 1798 1799 b) A prescription for Schedule III, IV and V drugs may be transferred only from the 1800 original pharmacy and only one time for the purpose of original fill or refill 1801 dispensing and may not be transferred further. However, a pharmacist who is 1802 electronically sharing real-time on-line computerized systems may transfer up to 1803 the maximum refills permitted by law and the prescriber's authorization in accordance with CFR 1306.26(a). 1804 1805 1806 c) Computerized systems must satisfy all information requirements of this Section, 1807 including invalidation of the original prescription when transferred between pharmacies accessing the same prescription records or between pharmacies of the 1808 1809 same ownership. If those systems that access the same prescription records have 1810 the capability of cancelling the original prescription, pharmacies using such a system are exempt from the requirements of this subsection if the transferred 1811 prescription can always be tracked to the original prescription order from the 1812 1813 prescribing practitioner and the original prescription can be produced. 1814 1815 d) When prescription information is transferred to another pharmacy for the 1816 purposes of original fill, the transferring pharmacy must enter a prescription into its system as if that prescription were filled at that pharmacy. 1817 1818 1819 e) Nothing in this Section shall apply to transactions described in Section 20 of the 1820 Act. 1821 1822 f) A prescription shall only be transferred upon the request or authorization of the person for whom the prescription was issued, except upon closure of a pharmacy, 1823 1824 in which case notice shall be made to that person, orally or in writing, of the 1825 closure and the location where the prescription is transferred. 1826 (Source: Amended at 47 Ill. Reg. , effective ) 1827 1828 1829 **Section 1330.760 Electronic Transmission of Prescriptions** 1830 1831 Electronic transmission of prescriptions shall be allowed, provided the following conditions are 1832 met: 1833 1834 The prescription shall be transmitted directly, or through an intermediary, from a) 1835 the authorized licensed prescriber to the pharmacy of the patient's choice. No 1836 intermediary shall alter the prescription information or content of the prescription. 1837 1838 b) The prescriptions shall comply with all applicable statutes and rules regarding the

| 1839         |                  | form, content, record keeping and processing of a prescription drug.   |
|--------------|------------------|--|
| 1840<br>1841 | c)               | The electronically transmitted prescription shall include the following:   |
| 1842         | C)               | The electromeany transmitted prescription shan metude the following.   |
| 1843         |                  | 1) The transmitting prescriber's facsimile number, if applicable;  |
| 1844         |                  | ine transmitting presenteer a ratesimile number, is approved,  |
| 1845         |                  | 2) The time and date of the transmission;  |
| 1846         |                  | ,  |
| 1847         |                  | 3) The identity of the person sending the prescription;  |
| 1848         |                  |  |
| 1849         |                  | 4) The address and contact information of the person transmitting the  |
| 1850         |                  | prescription.  |
| 1851         |                  |  |
| 1852         | d)               | The electronic device in the pharmacy that receives the electronically transmitted   |
| 1853         |                  | prescription shall be located within the pharmacy area.  |
| 1854         |                  |  |
| 1855         | <u>e)</u>        | The pharmacy has procedures in place for the cancellation of electronically  |
| 1856         |                  | transmitted prescriptions including the following:   |
| 1857         |                  |  |
| 1858         |                  | 1) A pharmacy using the National Council for Prescription Drug Program's   |
| 1859         |                  | SCRIPT standard for receiving electronic prescriptions must enable,  |
| 1860         |                  | activate, and maintain the ability to receive transmissions of electronic  |
| 1861         |                  | prescription cancellations and to transmit cancellation response   |
| 1862         |                  | transactions.  |
| 1863         |                  |  |
| 1864         |                  | 2) As soon as possible after the receipt of a prescription cancellation  |
| 1865         |                  | notification, but within two business days, pharmacy staff must either   |
| 1866         |                  | review the cancellation transaction to ensure that the prescription has been   |
| 1867         |                  | deactivated or ensure that deactivation occurred automatically.  |
| 1868         |                  | 2) Deligies and precedures to answer that the discontinued medications are   |
| 1869<br>1870 |                  | <u>Policies and procedures to ensure that the discontinued medications are not dispensed to a patient by a pharmacist.</u> |
| 1870<br>1871 |                  | not dispensed to a patient by a pharmacist.  |
| 1872         | <u>f</u> e)      | A facsimile of an electronically transmitted prescription shall be non-fading and  |
| 1873         | 10)              | remain legible.  |
| 1874         |                  | Temam legiole.   |
| 1875         | g <del>f</del> ) | The facsimile of the electronically transmitted prescription shall be stored in the  |
| 1876         | <b>∆</b> */      | pharmacy as required by State and federal laws or rules and may serve as the   |
| 1877         |                  | record of the prescription.  |
| 1878         |                  | · · · · · · · · · · · · · · · · · · ·  |
| 1879         | <u>h</u> g)      | The electronically transmitted prescription shall serve as the record of the   |
| 1880         | /                | prescription so long as the electronically submitted prescription can be stored and  |
| 1881         |                  | is readily retrievable so as to comply with federal and State record keeping   |

| 1882<br>1883                 |                  | requirements.  |
|------------------------------|------------------|--|
| 1884<br>1885                 | <u>i</u> h)      | To maintain confidentiality, adequate security and systems safeguards designed to prevent and detect unauthorized access, modification or manipulation of  |
| 1886<br>1887                 |                  | electronically transmitted prescriptions is required.  |
| 1888<br>1889<br>1890<br>1891 | j <del>i</del> ) | A pharmacy or pharmacist shall not enter into an agreement with a practitioner or healthcare facility concerning the provision of any means for the electronic transmission of prescriptions that would adversely affect a patient's freedom to select the pharmacy or pharmacy department of his or her choice. |
| 1892<br>1893<br>1894<br>1895 | <u>k</u> j)      | Electronically transmitted prescriptions for controlled substances may be dispensed only as provided by federal law.   |
| 1896                         | (Sour            | ce: Amended at 47 Ill. Reg, effective)   |
| 1897<br>1898                 | Section 1330     | 2.765 Requirements for Enrollment in Automated Prescription Refill Programs  |
| 1899                         | <u> </u>         | V. OO ZEOGWIZ GIROLO ZO  |
| 1900                         | Pharmacies p     | providing automated prescription refills, whether prescribed through electronic or   |
| 1901                         | -                | ptions as provided in Section 22c(a) of the Act, must:   |
| 1902                         |                  |  |
| 1903<br>1904                 | <u>a)</u>        | Require that the patient or patient's agent agree to be enrolled in the automated refill program for each prescription medication that the patient has been  |
| 1905                         |                  | prescribed.  |
| 1906                         | <b>b</b> )       | Ensure that only prescriptions which include an instruction from the prescribing   |
| 1907<br>1908                 | <u>b)</u>        | Ensure that only prescriptions which include an instruction from the prescribing health care provider that the medication can be refilled be eligible for the  |
| 1909                         |                  | pharmacy's automatic refill program.   |
| 1910                         |                  | pharmacy 5 automatic ferrit program.   |
| 1911                         | <u>c)</u>        | Require that the patient or the patient's agent sign a statement that they consent to  |
| 1912                         |                  | the enrollment in an automated prescription refill program for each medication for   |
| 1913                         |                  | which they enroll.   |
| 1914                         |                  |  |
| 1915                         | <u>d)</u>        | Maintain a record of the patient's or the patient's agent's signatures showing that  |
| 1916                         |                  | they consented to be enrolled in the automated refill program for each prescription  |
| 1917                         |                  | in which they are enrolled.  |
| 1918                         |                  |  |
| 1919                         | <u>e)</u>        | Maintain policies and procedures which require that upon the pharmacy's receipt  |
| 1920                         |                  | of a notice that the medication has been discontinued, the pharmacy staff take   |
| 1921                         |                  | prompt action to ensure that discontinued medications are not dispensed to the   |
| 1922                         |                  | patient under the automated refill program and that the patient's medication is  |
| 1923                         |                  | removed from enrollment in the automated refill program.   |
| 1924                         |                  |  |

|    | (Sour                  | rce: Ad          | lded at 47 Ill. Reg, effective)   |
|----|------------------------|------------------|---|
| Se | ection 1330<br>narmacy | 0.780            | Changes Change of Ownership, Name, Location, or Operations of a   |
|    | a)                     | A <del>-ne</del> | w pharmacy application must be filed whenever any of the following occur:   |
|    |                        | 1)               | 50% 10% or more of the ownership of the business, other than a publicly traded business, to which the pharmacy <u>license</u> was issued is sold or otherwise transferred to a person or entity that does not hold any interest in the business issued the pharmacy license prior to the sale or transfer; or |
|    |                        | 2)               | More than half the board of directors or executive officers of a business issued a pharmacy license <a href="mailto:changes;ehange">changes;ehange</a> .  |
|    |                        | <u>3)</u>        | Any change in the legal status of an entity;  |
|    |                        | <u>4)</u>        | Any change in location of a pharmacy, including remodel of the pharmacy or drug storage area;   |
|    |                        | <u>5)</u>        | Any change in the name of a pharmacy; or  |
|    |                        | <u>6)</u>        | Any change in the pharmacy operations pursuant to Subpart E of this Part or the Act.  |
|    | b)                     | •                | change of ownership of a parent company that owns a pharmacy shall not be idered a change of ownership of the pharmacy.   |
|    | <u>c)</u>              | The a            | application required by subsection (a) must be filed:   |
|    |                        | <u>1)</u>        | At least 90 days prior to occurrence of the change requiring the application for pharmacies located in Illinois.  |
|    |                        | <u>2)</u>        | No later than 30 days after the occurrence of the change requiring the application for pharmacies located outside of Illinois.  |
|    | <u>d)</u>              | partn<br>outst   | Division must be notified no later than 30 days after any change in owners, ners, members, officers, directors, or shareholders owning 5% or more of the anding shares occurs, or any other change in the information provided on the action not specified in subsection (a).                                 |
|    | (Sour                  |                  | mended at 47 Ill. Reg, effective)   |
|    |                        |                  |   |